HILL AND KNOWLTON

STUDY ON NUTRITIONAL, HEALTH AND ETHICAL CLAIMS IN THE EUROPEAN UNION

FOR THE EUROPEAN COMMISSION
DIRECTORATE GENERAL FOR HEALTH AND CONSUMER PROTECTION

April 2000

I. EXPLANATORY NOTE TO THE READER

The following notes will assist you in navigating around this study.

Hill and Knowlton (H&K) was commissioned by the Directorate-General responsible for Health and Consumer Protection of the European Commission (DG Sanco) to carry out a pan-European study on nutritional, health and ethical claims. This study was undertaken in the second half of 1999 and completed in early 2000.

The objective of the study was to provide comprehensive data on the legislation, rules and practices in place. In addition, the study was to seek the direct views of all interested stakeholders, namely regulators, industry and, in particular, consumers, to assess whether there are problems of misleading claims endangering consumer protection.

The research was carried out in order to examine whether and, how, the Misleading Advertising Directive (84/450) could be used to resolve the problems encountered as a result of such claims (it should be noted that a study on green claims has already been completed). More specifically, it looked at whether the Directive could be amended to secure higher consumer protection, thereby creating a framework for all types of claims. DG Sanco is fully aware that nutritional and health claims are "vertically" regulated by the Nutritional Labelling Directive 90/496 and the Labelling, Presentation and Advertising of Foodstuffs Directive 79/112 respectively (although this Directive's reference, since its consolidation, is now 2000/13). Hence, the challenge to find a way of "horizontally" regulating all types of claims. Thereafter, further changes to current legislation could follow, based on the individual type(s) of claim(s).

H&K interviewed over 200 stakeholders (logged into the database of contacts) across the 15 Member States, the United States, Canada and at the EU level (Brussels-based organisations). H&K has tried its best to seek the views of as many stakeholders as possible and would like to thank all those who very kindly participated and apologise to those which may have been left out. Whilst every effort has been made to ensure that the study reads correctly in English, please note that many sections were undertaken by non-native English mother-tongue persons. DG Sanco also made available to H&K the answers received in reply to the questionnaire they sent out to the Member States in 1988 as a first initial assessment of the situation.

The focus was to study not only what is in place and how it is working but, more importantly, what developments are taking place and what are the views of the stakeholders, in particular consumers. The findings of the study have led us to make a number of recommendations aimed at ensuring better regulation of claims at the EU level to guarantee consumer protection and to establis a clearer regulatory framework in which industry can operate.

If one agrees with the analysis that claims must be better regulated at EU level, a number of specific horizontal and vertical solutions need to be put in place. This will require the Misleading Advertising Directive to be amended to introduce across the board measures. But also, amendments to Directives 90/496 (nutritional labelling) and

to 79/112 (food labelling), defining what is a foodstuff in the context of the general review on foodlaw, and providing an EU-wide information campaign.

There are six main sections to the study, including the Explanatory Note.

The Analysis and Recommendations provides a global view of the whole study, divided into the following sections:

A. Analysis (main findings)
    1. Consumers and Consumer Protection
    2. Member State Legislation and Definitions
        a. Nutritional Claims
        b. Health Claims
        c. Ethical Claims
        d. Definitions
    3. Voluntary Codes of Practice
    4. Verification Systems
        a. Substantiation
        b. Pre-Clearance
        c. Post-Clearance
        d. Legal Persons Entitled to Take Legal Action
        e. Burden of Proof
        f. Applicable Penalties
    5. Trade Barriers
    6. Means of Communication
    7. Case Law
    8. Statistics
B. Recommendations
    1. Horizontal Approach - Amending the Misleading Advertising Directive
    2. Vertical Legislation - Amending 79/112 and 90/496
    3. Other Measures

The Comparative Analysis brings together all relevant information obtained from the 15 Member States, the US, Canada and the European Union/Brussels, grouping it under a number of subject categories (see below).

The Country Reports provide the detailed factual information as to what is happening on the ground. We have reviewed all 15 Member States, the US, Canada and the European Union level. The following structure has been used for each country report: each sub-section covers each of the three claims (i) nutritional; (ii) health; and (iii) ethical claims.

I. Executive Summary

This section, which reflects the standard structure of the individual country reports as well as focusing specifically on consumer protection, aims to provide an overview, containing all the key information, together with our initial assessment of what the key stakeholders would like to see.

II. Member State Policy

The purpose of this section is to provide information in Member States' laws and regulations, their current policy thinking and their plans and wishes for the

future. It also provides details of the views and positions of the other key stakeholders; namely consumer organisations, the enforcement authorities and industry.

A. Definition of Claims

One of the key problems is the lack of definitions, legal or not, in particular with regard to health and ethical claims and assessing whether there is any commonality.

B. Legislation in Place

We examine the regulatory framework, the legislation in place, most of which is implementing EU Directives, and assessing whether they conform.

C. Existing Prohibitions, Restrictions and Exemptions

D. Policy Developments and Stakeholders' Positions

This is one of the most important sections as it provides details of the main stakeholders' positions on the current situation and their intentions (policy orientations and/or proposals), whether they wish to see further regulation and whether this would be at EU level.

III. Voluntary Instruments

To assess why and how voluntary agreements/codes of conduct have come about – do they suggest that legislation is insufficient/no longer appropriate.

A. Voluntary Instruments in Place

B. Definitions used in Voluntary Instruments

C. Existing Prohibitions, Restrictions and Exemptions

D. Voluntary Instruments Accepted/Recognised by the Authorities

IV. Verifications Systems

To assess what systems are in place and, secondly, whether they are effective in contributing to consumer protection.

A. Criteria for Substantiating Claims

B. Legal/Administrative Systems for Verifying Claims

C. Pre-Clearance Rules/Guidelines

D. Post-Clearance Rules/Guidelines

E. Legal Persons entitled to Take Legal Action

F. Burden of Proof

G. Applicable Penalties

V. Case Law

To assess what case law exists in order to provide an assessment of the misleading claims which exist and to assess how courts interpret EU and national legislation on claims.

VI. Means of Communication

This section aims at assessing whether legislation on claims differs depending on the way claims are communicated, e.g., radio/labelling, etc.

VII. Statistics on Claims

This part was supposed to provide data on misleading claims although, unfortunately, this information is virtually non-existent.

VIII. Annexes

Each Country Report is backed-up by all relevant information which is contained in the Annexes, which are not part of this report due to the enormous quantity of paper. These were submitted in a separate set of binders. However, each country report contains a full list of the annexes submitted.

Database of Contacts. In carrying-out the study, Hill and Knowlton interviewed over 200 persons from Government/Administrations, consumer organisations, industry and other interested/relevant partie and whose details are contained in an Access Database.

ACRONYMS INDEX

To guide you through the study, we provide below the full names of the most referred to organisations:

- BEUC, The European Consumer Association
- CIAA, Confederation of the Food and Drink Industries of the EU
- Codex, Codex Alimentarius
- Eurocoop, The Association of European Consumer Cooperatives
- EHPM, The European Health Product Manufacturers' Association
- Eurocommerce, The European Retailer Association
- ILSI, International Life Sciences Institute
- EASA, European Advertising Standards Alliance
- FLO, Fairtrade Labelling Organizations International
- EJC, European Court of Justice
- EFLA, European Food Law Association
- FUFUOSE, The European Commission Concerted Action on Functional Food Science in Europe
- CEEREAL, The European Breakfast Cereal Association
- EFTA, The European Fair Trade Association
- EURATEX, The European Apparel and Textile Organisation
- ETUF:TCL, The European Trade Union Federation of Textiles, Clothing and Leather
- ILO, International Labour Organisation

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II. ANALYSIS & RECOMMENDATIONS

In this section, we provide in part A an overall analysis of the key findings and in part B we spell out our suggested recommendations. There is some repetition as we felt it important to recap on the key findings in order to explain the reasoning behind the recommendations proposed.

A. ANALYSIS

1. CONSUMERS AND CONSUMER PROTECTION

Do nutritional, health and ethical claims create consumer protection problems? For consumer organisations they do and many regulators share this view.

Whilst there are no available statistics as to how many claims exist, few would dispute the fact that there is a proliferation of claims being made today. Consumer organisations go from the premise that as soon as a misleading claim has been made, the damage has effectively been done, undermining consumer protection. Also, the legislation in place or the lack of a clear regulatory framework has led to misleading claims being made. Whilst there is not a plethora of evidence on misleading claims, it is evident that the Member States' enforcement authorities are very often called upon to negotiate with the makers of claims in order to stop misleading claims. Hence, consumer organisations are calling for proper and effective control.

Consumer organisations, not surprisingly, are less well resourced than industry and less well informed about the issue of claims than are the regulators. We interviewed all the major consumer organisations throughout Europe and what is striking is that only a few are fully briefed on the issue and have defined positions. To date, BEUC is studying the issue of claims (and health claims in particular) intensively, but does not as yet have an officially published position. For consumer organisations, this is becoming one of the key concerns as it relates to the bigger picture of food safety. The most organised of consumer groups are in the Nordic countries, Germany and especially in the UK, where the associations have clearly defined positions and are active in seeking changes to protect the consumer.

As to the three categories of claims, consumer organisations agree that whilst it is health claims which are creating the greatest problems, a closer look at nutritional and ethical claims is essential.

As to health claims, the crucial factor into why misleading claims come about is the outdated and unclear legal framework. Member States interpret Directive 79/112 and its Article 2 either more liberally or restrictively, leading to industry making claims, which are acceptable in one country but not in another (see below barriers to trade section).

Consumer organisations are calling for checks and balances to be introduced. Nobody disagrees with this principle. It is the how, which tends to pit industry against consumers. It is up to the regulators to find a solution and according to the research, virtually all stakeholders, and consumer associations in particular, agree that this is an issue to be resolved at the EU level.

Due to the lack of a clear regulatory framework, a number of voluntary Agreements have been set-up, often as a stopgap, until further legislation is adopted. Consumer associations have been following the developments surrounding the different national voluntary agreements which have been put in place, not least the recent and much awaited UK Joint Health Claims initiative, where they acted as equal representatives. The consumer contribution to these initiatives has certainly been welcomed by the parties concerned as regulators and industry agree that a tripartite balance is needed (see Voluntary Agreement section below).

As to nutritional claims, consumer organisations, particularly in the UK, make a valid point about the need for further clarification and the need for further substantiation. Industry in several Member States also suggest that additional guidelines are required.

Ethical claims, from a consumer protection angle, do not currently pose a problem in that there are very few being used. Nevertheless, consumer groups are concerned for the future, as there is general agreement that their use will proliferate and, thus, lead to misleading claims being made. Hence, consumer organisations argue that they should also be appropriately regulated. The European Commission concluded in its Communication on Fair Trade of November 1999 that there was a need to further study and review how fair trade claims and labels are currently substantiated, verified and controlled. It also concluded that the Directive on Misleading Advertising "could be considered as an instrument for ex-post verification and control in order to ensure adequate protection for consumers".

In summary, consumer organisations across Europe are calling for strict EU legislation to introduce: pre-clearance of any claims; precise substantiation criteria to allow a claim to be used; reinforced post verification systems; a shift in the burden of proof onto the shoulders of the maker of the claim; and better consumer information about the relationship between diet and health. These points are developed below.

2. MEMBER STATE LEGISLATION AND DEFINITIONS

The first point to make is that there is no legal definition of what a “claim” is at either national or EU level. Codex Alimentarius does nevertheless provide a definition of a claim for the food sector. The EU Misleading Advertising Directive 84/450 does not directly refer to claims, but it is generally acknowledged that claims fall under its scope.

a. Nutritional Claims

As regards nutritional claims, all definitions are, by and large, the same and follow the Codex guidelines, which define four different types of claims (nutrient content, comparative, nutrient function and claims related to dietary guidelines of healthy diets). There is quite a large consensus that these should be now annexed to the Nutritional Labelling Directive.

There are also three countries where voluntary codes/guidelines have been set-up to provide further information to industry, namely in Denmark, Finland, and the UK,

such as the UK FAC guidelines, demonstrating the need to better assist industry in order to provide consumers with truthful information.

Another example is the Co-operative wholesale Society (CWS) in the UK, which has developed its own code of practice for labelling of pre-packed foods for both nutritional and health claims. The views of the CWS are that the lack of detailed provisions could lead to the potential misleading consumers.

It is our opinion that there is a need to clarify the EU Directive on nutritional labelling. As a first step, one should consider annexing the Codex guidelines tot he Directive. Secondly, nutrient content claims must be clearly defined in terms of the quantitative level of the nutrient present, be consistent between products, and be meaningful to consumers.

b. Health Claims

Without a doubt, health claims pose the major problem and the major challenge. Health claims are interpreted differently: either a more liberal regime such as in the UK or a restrictive/to the letter of the law such as in Germany and Italy. Also, the various developments taking place throughout Europe (e.g., the establishment of voluntary codes of conduct) are clearly indicative of the need to establish a better regulatory framework.

The draft April 1999 Codex Alimentarius guidelines on the use of enhanced function claims and reduction of disease risk claims (even if they go further than the allowed scope of Directive 79/112) have received wide support from both industry and Member States authorities.

Also, the developments across the Atlantic in both the US and Canada are demonstrative of the liberal approach to health claims gaining ground.

With the acknowledged relationship between diet and health, industry has been innovative, introducing new foods and a range of fortified foods. However, Directive 79/112 effectively puts the brake on innovation at a time when consumers are asking for quality and healthy food products. There is perhaps a case to be made for allowing “enhanced function claims” and “disease risk reduction claims”, albeit with proper controls”.

The European Commission announced in its White Paper on Food Safety that it will look into the question of nutritional claims and functional claims. Unfortunately it is not clear what is meant by 'functional claims'. More clarity could have been achieved, if the Commission had adopted the terms currently used in international fora such as the Codex Alimentarius and Council of Europe i.e. "enhanced function claims" and "disease risk reduction claims.

The voluntary codes/agreements set-up in Sweden, Spain, The Netherlands (already in operation) and in Belgium and in the UK (both expected to become operational in 2000) is a clear demonstration of how regulators, industry and, to a large extent, consumers have come together to pave the way forward. The definitions, criteria,

verification systems established in these voluntary codes/agreements should be viewed as a blue print for what should be done at EU level.

Whilst nutrition claims are defined by Directive 90/496 on nutrition labelling, there is no definition of health claims. In order to be able to make claims that go beyond 'normal' nutrition claims (as defined by Directive 90/496), there seems to be a tendency by industry to make claims that lie between nutrition claims (as defined by Directive 90/496) and the prohibition set out under Directive 79/112. This legally somewhat undefined zone (at least at EU level) is further complicated by the fact that Member States interpret differently the prohibition set out under Directive 79/112. Hence, the need for the EU to legislate on health claims.

As to the advantages of health claims for consumers, it is our opinion, based on the research carried out, that industry, regulators and even consumer organisations agree that health claims can be of benefit to the consumer. This is reflected in the liberal regimes of several EU countries; the growing number of voluntary agreements that allow for health claims to be made; the developments in Codex and the April 1999 draft guidelines which propose to allow health claims; and generally the widespread movement in the US and Canada to allow certain health claims. The issue is not whether to allow claims or not, it is how to control them and make sure that they do not mislead the consumer.

We are not suggesting the liberalisation of health claims. We are suggesting, instead, that by amending Directive 79/112 to allow health claims and to open-up the types of health claims, which can be made, this will create a proper regulatory framework for industry to work with. With it, of course, one must introduce the proper checks and balances to guarantee consumer protection.

The main demands of the stakeholders (majority view) are the following:

i. Consumer Organisations

- They are calling for action, preferably at the EU level, although this does not preclude action/measures at national level;
- They would prefer criteria for substantiation to be developed instead of a positive or negative list of health claims;
- They want pre-clearance for all claims;
- They want the supervision/control of claims once on the market to be tightened and want the enforcement bodies to be more aware and bring cases to court in order to guarantee consumer protection;
- They want the burden of proof to lie with the maker of the claim in order to allow for a more equitable and cheaper prosecution;
- They wish to see the EU setting-up an information campaign to educate and inform consumers on the advantages of diet and health; and
- They believe that current legislation is inadequate and/or incorrectly enforced and are, therefore, seeking change.

ii. Regulators

- Virtually all Member States (perhaps Spain and Belgium are somewhat more reluctant, and possibly The Netherlands does not see a great need) agree that it should be at the EU level that the problems surrounding health claims are resolved;
- The large majority of Member States have expressed the need to amend Directive 79/112 in order to meet current requirements;
- They consider Codex draft guidelines as the way forward in order to introduce new types of claims;
- They accept that perhaps a definition of a foodstuff should be elaborated to avoid the problem of borderline cases;
- They realise that they need to consider:
  - allowing enhanced function and disease risk reductions claims;
  - drawing-up a positive list of generic claims;
  - introducing pre-clearance generally or introducing pre-clearance for innovative claims; and
  - reviewing the criteria to establish what type of claim can be made.
- They view the voluntary codes/agreements as a step in the right direction but ultimately wish to see legislation in place.

iii. Industry

- They view the EU as the best level to create a clear regulatory environment;
- Whilst ideally industry would like to see self-regulation as the way forward, basing itself on the voluntary codes now in place, industry is also realistic and accepts that a code might not be able to work in each country (Italy and Germany for legal reasons) and the fact that regulators and consumers favour legislation;
- In addition, industry is calling for:
  - An amendment to 79/112, (and Directive 65/65) and Article 2 to allow new types of claims, in particular disease risk reduction claims and enhanced function claims;
  - The consideration of a clear set of criteria under which a claim can be made; and
  - No pre-clearance, but well defined post clearance verifications. This is one of the most fundamental issues and agreement on a way forward would go a long towards finding a compromise between what industry and consumers want. It is our opinion that industry's stance on pre-clearance is being reviewed/discussed and, hence, they may adopt a more realistic approach.

- Retailers and other industry-related interests favour only enhanced function claims and call for criteria to be drawn-up under which conditions a claim can be made (a positive list is possible).

- The advertising industry in general favours self-regulation.

c. Ethical Claims

Ethical claims, which are generally seen to cover labour related working conditions and are a fairly new type of labelling, have only appeared on products in the last few years. Furthermore, there is currently no direct legislation or legal definition in any of the Member States. Nevertheless, each Member State has legislation which indirectly applies to ethical claims, most often due to national implementation of the EU Directive on Misleading Advertising.

It must be said that, currently, consumer groups do not see a problem in the use of ehtical claims, mostly because so few are being used. Nevertheless, consumers and many of the other stakeholders agree that they should be regulated in order to avoid problems and guarantee consumer protection in the future, given the expectation that they will proliferate. Amongst the stakeholders that do not perceive a need for regulation on ethical claims is the retail sector.

It is important to note that two countries (Belgian and Italy) are drafting legislation. Four other Member States (Denmark, France, Portugal, and Sweden) have seen developments signalling a call to regulate ethical claims in some form. The other nine Member States have not considered the issue and, hence, have no defined position.

Voluntary agreements/codes of conduct are being set-up for ethical claims. The most well known one is the Fairtrade Labelling Organisations International (FLO), which does not have a claim as such but a fairtrade label, which could be/is associated by consumers with certain ethical standards.

On the whole, consumer organisations have not developed a defined viewpoint/position on ethical claims. Suffice to say that they want them to be controlled, like any other claim, via the right channels. By contrast, as a whole, industry does not perceive ethical claims to be an issue, as they are very limited in use, and believe that the market will regulate their use.

d. Definitions

Currently there exists no legal definition of what a "claim" is. In order to clarify this aspect of the Misleading Advertising Directive, we would recommend the introduction of a definition of claims. In the light of policy developments and based on the stakeholders' position, we also consider necessary a definition of:

- a health claim;
- a foodstuff; and
- an ethical claim.

3. VOLUNTARY CODES OF PRACTICE

It is indicative that where there is clear legislation, there are virtually no voluntary codes of practice, but where legislation is non-existent, i.e., on ethical claims, or where legislation is perceived to be outdated or no longer appropriate, i.e., health claims, the proliferation of voluntary initiatives is considerable. The exception is perhaps Sweden where the industry-led voluntary agreement emanated from the view

that health claims used in a responsible way might be an important means of helping to implement the Swedish dietary recommendations.

With regard to nutritional claims, only Denmark has a voluntary agreement in place. In Finland and the UK, the relevant authorities issue clarification guidelines. This is indicative of the need to provide industry further information as to what they can and cannot do and, hence, raises the issue as to whether this might cause consumer protection problems.

With regard to health claims, several voluntary agreements are in place and/or are being planned. Sweden is home to the oldest code of conduct on health claims, which entered into force in 1990. Spain and The Netherlands have codes already in place and in Belgium and the UK codes are being finalised.

The UK code is an example of a possible way forward on how to create a framework for health claims. The majority of stakeholders in the UK are hoping that the Joint Health Claims Initiative (JHCI) will provide the necessary framework for regulating health claims. However, a number of the participants believe that it is a stopgap until a proper legislative framework, which should emanate at the EU level, is established.

The JHCI can claim that all interested parties (government, enforcement authorities, consumers and industry) participated actively and they are now hoping that it will come into force in 2000. A Code Administration body, made up of a Council (representing all key stakeholders), a Secretariat and an expert authority will manage the JHCI. Consumers, especially, hope that the Food Standards Agency will take responsibility. The initiative promotes a pre-market advice/pre-vetting system, which suggests the exercise of due diligence, applied to health claims in all means of communications, with the overriding principle that the likely consumer perception of the health claim is paramount. The Code administration body will develop a list of generic health claims, to be approved by the Expert authority, to be reviewed regularly. A system of innovative claims will also be established. Whilst not legally binding, it promises to deliver.

The Swedish code is another blue print for what could be done at the EU level. It ensures that health claims must be based on the importance of the product in a balanced diet, and must be in line with official Swedish dietary recommendations. The claim must consist of two parts: A: information on diet-health relationship: B: followed by information on the composition of the product. To be noted is that the two main Swedish consumer organisations support the voluntary code and have pronounced themselves in favour of the updating of this code concerning product-specific physiological claims.

Interestingly, the consumer organisations have been involved to a degree in the elaboration of these voluntary agreements. In the UK and Sweden, they have been partners in the elaboration of the codes and are supportive on the whole. Admittedly, in the UK, the consumer organisations wanted a system of pre-clearance, which was finally not retained in the code. Consumers were also active in the draft Belgian voluntary code, but are currently hesitating to join. The Dutch Consumer Association was (and is) involved in the elaboration of the Dutch Advertising Code and on the Code of Practice on Health Benefits Claims.

Whilst not a voluntary agreement in itself, the Recommendations made by the French Conseil National de l'Alimentation, following an extensive and broad-based consultation process, including consumers, provides a valuable insight into how the major stakeholders in France would like to address the issue in the future at the European level. Some of the 12 key points of the recommendation are in line with consumer wishes.

Due to the fact that more and more stakeholders consider that some health claims should be allowed, such codes have proliferated across the EU, thus giving a different interpretation to Directive 79/112, in effect broadening its scope and by default defining a health claim. The voluntary agreements, by their nature, do not however have effective and/or binding sanctions. Nevertheless, all set out detailed criteria for substantiation.

As to ethical claims, being the most recent type of claims made, numerous codes exist. These codes do not specifically deal with claims, but rather set-up labelling initiatives and set out certain criteria that have to be respected, in order to use the logo/symbol of these labelling initiatives. These are mostly fair trade labelling initiatives.

There exist also a number of voluntary agreements on advertising in general in nearly all Member States, which are aimed at providing a sort of voluntary framework to keep advertising within accepted moral and ethical boundaries.

The question can be raised as to how far the proliferation of national voluntary agreements (in particular in the area of health claims) does not lead to different levels of consumer protection within the EU, as well as to the creation of new barriers to trade. Another possibility would be to model consumer protection in the area of claims after the new approach in harmonisation used for technical legislation, i.e. EU legislation only establishes the general principles and essential requirements. For the technical details, reference is made to standards due to be established by standardisation institutes (e.g. CEN), following a mandate from the Commission. As in the technical area under this scenario, if standards are met, there would be a presumption that the claims used are in conformity with the essential requirements for claims as set out in an amended Misleading Advertising Directive.

4. VERIFICATION SYSTEMS

Verification systems encompass, from our perspective, five components, which hold the key to how any type of claim can be better regulated, via amendments to the Misleading Advertising Directive. This is also the key to guaranteeing increased consumer protection.

a. Substantiation

Consumer organisations have clearly called for increased substantiation of claims and, in recent initiatives, the voluntary codes have developed explicitly detailed criteria.

As regards nutritional claims, national legislation most often only applies the criteria set out in Directive 90/496 on Nutritional Labelling, i.e. whenever a nutritional claim is made nutritional labelling becomes compulsory. In some countries additional guidelines (e.g. Finland) and/or legal requirements exist as to the composition of the product which have to be respected, in order to be able to make certain nutritional claims (e.g. UK, Germany).

Regarding health claims, in many cases, criteria for substantiating them do not exist by law, as health claims are simply not allowed, or criteria only apply for some exceptions, which are allowed for foodstuffs for particular nutritional uses (PARNUTS). In these cases, a manufacturer has most often to submit the label and information on the composition of the product. In some Member States and, in particular, in those where a pre-clearance for health claims exist (Austria, France) criteria have been set out for substantiating claims. Here again, in general the label and information on the composition of the product has to be submitted. Furthermore, some countries also require scientific data to be submitted (e.g., France).

All voluntary instruments on health claims require, in general, the submission of scientific evidence. The voluntary instruments define very often in more detail the criteria that the scientific evidence has to fulfill. Most interesting in this respect is the CIAA code on health claims, which lists a large number of criteria that have to be met in order to substantiate a claim.

Substantiation criteria for ethical claims only exist in the voluntary agreements. Fair trade labelling schemes apply, in general, the criteria set out by the Fair Trade Labeling Organisation (FLO). These criteria are normally: purchase only from accepted sources; payment of a premium in addition to the market price; respect of minimum labour standards; etc.

It is clear that a substantiation system needs to be elaborated as one of the pre-conditions for allowing claims. We would recommend introducing into the Misleading Advertising Directive (for example in the form of an Annex) a number of criteria that need to be fulfilled in view of the substantiation of claims. It is clear that for the use of health claims more detailed criteria as to the scientific substantiation should be set out. This has been done in a number of voluntary codes on health claims. In our view, such detailed criteria could be addressed under Directive 79/112 and/or through the elaboration of technical standards.

b. Pre-Clearance

While in most Member States no pre-clearance rules apply by law, there exist in most of them informal pre-clearance rules, whereby companies can ask their local enforcement authorities to verify in how far the claims that the producer wants to use may be considered lawful. This informal procedure, however, offers no guarantees but according to the enforcement authorities enables them to stop many misleading claims being used.

In some Member States, which rely on self-regulatory instruments such as the UK, Ireland and The Netherlands, more formalised pre-clearance rules exist but, which are equally not set out by law.

Most interesting in this respect is the UK's Joint Health Claims Initiative. The draft code introduces the possibility for companies to ask for pre-market advice for innovative health claims. Whilst the opinion of the JHCI will have no legal right, companies which receive a positive answer from the JHCI, may be looked upon favourably by the courts should a case arise. Acting upon pre-market advice suggests the exercise of "due diligence". The courts may take this into account in the event of any legal challenge to the health claim under the Food Safety Act.

Systems of pre-clearance have been set up in France and Austria, whereby authorisation from the relevant administrations are needed, in order to be able to make health claims. By contrast, in Germany pre-clearance is considered censorship and is, therefore, not applied.

Consumer associations are widely in favour of pre-clearance with regard to health claims in order to ensure that only truthful and non-misleading claims are being used. Their view is that once a misleading claim has been made, the damage has been done, even if the claim is then pulled off the market. By contrast, industry, has indicated that it was in general opposed to pre-clearance procedures, as:

- these would delay the placing on the market of a product;
- it was not possible to copyright final food products and/or the claim made;
- industry was worried that confidentiality was not ensured during an a priori approval procedure; and
- it was unproportional to introduce a strict system of pre-clearance.

Suffice to say that if pre-clearance were to be introduced, it would most probably avoid to a large extent misleading claims coming onto the market. Nevertheless, this is one of the major stumbling blocks between industry and consumers. Hence, the pre-clearance system will have to accommodate industry's needs for a quick, efficient, confidential system. Here lies one of the greatest difficulties that the EU Commission will have to face.

Whilst one could envisage making use of the European Food Authority that has been announced in the White Paper on Food Safety as the authority responsible for pre-clearance, this has two disadvantages. Firstly, the European Food Authority would only be a possible way forward for claims made on foodstuffs and secondly, the European Food Authority as envisaged by the White Paper would not have any regulatory powers. This means that whilst the evaluation of claims could be done by the European Food Authority, the final decision to allow a claim or not would still have to be taken by the European Commission.

c. Post Clearance

Post-clearance is, in general, undertaken by the relevant health or food inspection services. In some countries also the authorities dealing with trading standards are responsible for post-clearance (e.g., UK, Portugal).

In a number of Member States formalised out-of-court post-clearance systems apply, mostly in the framework of voluntary codes on advertising (e.g. Germany, Greece, Italy, Ireland, etc.). It seems that competitors quite often make use of these systems.

Consumer associations and regulators/enforcement bodies are critical of how difficult post verification is. Hence, if pre-clearance could be introduced, this would already make post-clearance less of a burden.

Nevertheless, better systems need to be put in place to assist the enforcement authorities in carrying-out their post clearance checks. Interlinked with this issue is, of course, the crucial issues of who is entitled to take legal action, the burden of proof – on whose shoulders does it lie - and what applicable sanctions can be levied. These points are developed in the next sections.

d. Legal Persons Entitled to Take Legal Action

In all Member States, the authorities, companies and consumer associations are entitled to take legal action. The only exception is Austria, where so far consumer associations are not allowed to take legal action. Nevertheless, the Austrian Law against Unfair Competition is currently being revised, in order to give consumers the right to take legal action. There are a few countries (Austria and Germany), which do not allow the individual consumer to take legal action, but they do not see this as having led to any problems in terms of consumer protection.

We consider that no clarifications/changes need to be made to the Misleading Advertising Directive with regard to the legal persons entitled to take legal action.

e. Burden of Proof

The burden of proof lies, in a majority of Member States, with the plaintiff. Nevertheless, some Member States have established a system whereby the burden of proof lies with the maker of the claim, in the case that the authorities start an investigation. The latter is reflected in the Misleading Advertising Directive, which empowers, under certain circumstances, national courts and administrations to require advertisers to furnish evidence as to the accuracy of factual claims in advertising.

It is only in the Nordic countries that the burden of proof lies clearly with the maker of the claim. In Germany, it was reported that the burden of proof is creating problems for consumer associations wishing to pursue cases in front of the courts, as they do not have the means of paying an expert who could provide an opinion testifying that a certain claim could not be scientifically proven.

Also, the enforcement authorities, in particular in the UK, have highlighted the fact that taking a manufacturer to court requires enormous resources, which they do not have. Hence, unless they are 100% confident of their case, they will not go to court, but rather enter into negotiations with the maker of the claim to try and resolve the issue out of court. This process can take considerable time and the claim can still be on the market whilst the negotiations are going on. It is difficult to indicate what the

extent of out of court settlements is, but we are of the opinion that they are numerous.

Clearly, in those countries where the burden of proof lies with the plaintiff, there seem to exist problems in terms of bringing cases to the courts. Consumer associations are unanimously in favour of a reversal of the burden of proof and even industry, in general, seems to agree that a manufacturer needs to be able to justify nutritional and health claims with scientific evidence.

In essence, we believe that a modification of the rules on burden of proof, as set out in the Misleading Advertising Directive, should take place. All arguments taken into account, the optimal solution is, in our view, a reversal of the burden of proof, i.e. it would be up to the maker of the claim to prove that his/her claim is non-misleading and truthful. Nevertheless, a reversal of the burden of proof may be considered by some Member States as a profound intervention by the EU into its basic legal principles. In this case, we consider as second best option to make the reversal of the burden of proof dependant as to whether the producer has fulfilled certain criteria set out in an amended Directive on Misleading Advertising, whilst at the same time requiring the maker of the claim to provide all useful documentation and information so that the plaintiff can avail himself of concrete facts to prove his case.

f. Applicable Penalties

In all Member States fines and/or imprisonment are foreseen as penalties for misleading advertising and/or non-respect of food labelling rules. Nevertheless, in some Member States the penalties/fines seem to be less stringent than in others. The Misleading Advertising Directive only foresees that Member States set up a system which allows for the cessation of the misleading advertising.

In order to guarantee the same level of consumer protection in all Member States with regard to the sanctioning of misleading claims, one option could be to introduce a provision into the Misleading Advertising Directive, requiring Member States to introduce effective and dissuasive sanctions against the use of misleading claims.

5. TRADE BARRIERS

Barriers to trade are not seen to give rise to consumer protection problems.

Nevertheless, manufacturers are experiencing trade barrier problems as a result of health claims. Some problems were reported for nutritional claims where the reference values for making a nutritional claim differ between Member States, but none for ethical claims.

It is interesting to note that barriers to trade were mentioned in those countries that have a very strict interpretation of health claims (e.g., Austria, Italy) and in those countries that have a pre-clearance system in place (e.g. Austria, France). Furthermore, some barriers to trade were reported by the authorities, where food supplements being imported from other countries are often categorised as medicinal products (e.g., Germany, UK). In general, and quite logically, barriers to trade seem to

appear between countries that share the same language, e.g., Austria and Germany, or the Flemish part of Belgium and The Netherlands.

Industry indicated that often these barriers to trade would not be visible, as industry tended to modify its labelling from one country to another, instead of going to the courts. Barriers to trade seem to be generated mainly by the different interpretation that Member State authorities give to the ban spelled out in Article 2 of Directive 79/112, i.e. the prevention, treatment and curing of disease, as well as to the development of voluntary agreements on health claims.

An amendment to the Misleading Advertising Directive will not resolve these trade barrier problems. In our view, these problems could essentially be resolved through an amendment of the Labelling Directive 79/112. It would be necessary to clarify the scope of its Article 2 and align it with the developments taking place within Codex Alimentarius, as well as national voluntary codes on health claims.

6. MEANS OF COMMUNICATION

Claims can be made through different means of communication. The most common means are the labelling of the product and advertising. The countries studied do not differentiate between legislation applicable to labelling and legislation applicable to advertising. In addition to the legislation, self-regulatory rules apply to advertising in certain instances, but none exist for labelling. This, however, does not reflect a difference between the means of communication, since national legislation remains applicable to both labelling and advertising.

On many occasions, the Internet has been described as a potential source of problems because of the quasi-impossibility of monitoring the claims made on the web, as well as the difficulty of controling electronic commerce of products bearing prohibited claims. However, policy thinking on this issue is still at a very early stage and no country has taken measures that would apply specifically to the Internet.

It is unclear whether the scope of the Misleading Advertising Directive encompasses all means of communication and, in particular, claims made on labelling (on-pack claims). All national legislation is based on the principle that a uniform set of rules should apply whatever the means of communication used. We, therefore, recommend that the Directive be amended so that it clearly applies not only to advertising but also to labelling.

7. CASE LAW

Whilst case law on claims – virtually all were on health claims – were identified, these are limited for three reasons:

1. There seems to be in many Member States a tradition of resolving disputes outside the courts on an informal basis. In particular, in countries which rely heavily on self-regulation (e.g. the UK), disputes tend to be resolved outside the legal system.

2. In some countries, there seems to be a problem for consumer associations and/or local authorities to bring cases before the courts. This is due to a number of

reasons but the most important appears to be cost and the difficulties in securing a judgement as a result of the burden of proof being on the plaintiff.

3. In countries with a strict legislation and interpretation of health claims by the authorities, producers tend to clarify with the enforcement authorities beforehand, in an informal way, in how far there may be objections by the authorities on the use of a certain claim.

Although it is difficult to draw general conclusions from the limited case law that exists, it seems that courts tend, in general, to adopt a rather strict interpretation of health.

The European Court of Justice (ECJ) has ruled on a number of cases, which concern the classification of medicines. It is in this context that the Court has also looked at health claims. The rulings indicate that the ECJ gives a broad interpretation to Directive 65/65 on medicinal products, i.e. a product recommended, as having prophylactic or therapeutic properties is a medicinal product, even if it is generally regarded as a foodstuff. In a more recent case, the ECJ seems to consider that a control system for claims as foreseen under the Misleading Advertising Directive (i.e. that courts and administrations can ask advertisers to furnish evidence as to the accuracy of factual claims, taking into account the legitimate interest of the parties involved) is a viable way of controlling claims.

In a number of Member States, disputes are more often resolved in an informal way outside the courts. In order to make such a system work in all Member States, it may be considered to introduce in the Misleading Advertising Directive a similar system as foreseen under Directive 98/27 on Injunctions for the Protection of Consumers' Interests. This Directive foresees that the party that intends to seek an injunction can only start this procedure if it has tried to achieve the cessation of the infringement in consultation with either the defendant or with both the defendant and a qualified entity (i.e. public bodies and organisations whose purpose it is to protect collective interests of consumers).

8. STATISTICS

As to the availability of statistics providing an overview of the complaints that have been submitted by consumers to the authorities, courts or out-of-court bodies, as well as the number of claims made, little information was available from either the authorities or consumer/industry associations. We summarise below the available country information:

Austria

In Austria a pre-clearance for claims applies. According to the Federal Chancellery, the claims for which an authorisation is requested most frequently are claims in line with current trends (i.e. staying fit, losing weight) such as "reduces weight" or "encourages digestion". On average 1,000 to 2,000 authorisations are requested per year and about two-thirds are granted after modification (which is often substantial).

Finland

According to the National Food Agency (NFA), there have not been any decisions or court cases on an inappropriate use of health claims in foodstuffs since 1995 (before 1995 the Consumer Ombudsman had the responsibility for the market control of claims). Since 1995, the NFA has passed comments on unsuitable claims in ten instances. However, in all these cases the claims have been corrected without further action and, therefore, the NFA is not willing to list them. There have also been a few cases where health claims have been used in an inappropriate way in the marketing of dietary supplements.

Germany

One of the best sources proved to be the Centre for the Fight against Unlawful Competition. The Centre received, in 1998, a total of 21,190 complaints relating to unlawful competition Out of these, the Centre estimates that around 1,300 complaints concerned health and disease related advertising. More specifically concerning food-related claims, the Centre estimates that around 100 complaints are received each year, of which only three concern complaints on nutritional claims. The rest concern health claims where the complaints were mostly settled out of court.

Another very useful source proved to be the Consumer Protection Association in Berlin. It has a database that goes back to 1992 and tracks all the letters it has sent to companies asking for declarations for forbearance. The Consumer Protection Association indicated that its database contains around 150 such admonitions covering health related advertising, of which 80 concern advertising for slimming products.

The German Advertising Council also has some statistics regarding complaints that are being submitted. In 1997, the number of complaints received concerning foodstuff advertising was 23. But this number went down to eight in 1998. The statistics, unfortunately, do not reveal how far these claims concerned health claims or other sorts of complaints related to food advertising.

Italy

Real statistics on nutritional and health claims were not available. However, the Antitrust Authority responsible for misleading advertising has published some data.

In the period 1992-1997, the Antitrust Authority analysed a growing number of cases related to misleading advertising. The number of cases which have been recognised as misleading increased from 1992, where 35% of the cases analysed turned out to be misleading, to 73% in 1996, with more than 350 cases examined.

The areas which presented the highest rates of misleading advertising per number of cases analysed in the period May 1992-April 1997 are:

- Instructions and publishing, with more than 150 cases analysed and around 67% of the cases found misleading;
- Trade, with more than 130 cases, and around 69% found misleading;

- Cosmetic and health care, with more than 100 cases, and around 70% found misleading;
- Tourism and travel, with 60 cases, and 38% found misleading
- Food, with 42 cases and only 14% found misleading.

Portugal

The Portuguese consumer association (DECO) indicated the following statistics on labelling for cases where the association was invited to mediate in 1998 and 1999:

Complaints 1998	Nr. of complaints
Nutritional labeling	90
Health-related labeling	96
Ethical labeling	14

Complaints 1999	Nr. of complaints
Nutritional labeling	92
Health related labeling	74
Ethical labeling	27

For most of the cases, the problem was related to the fact that the labelling was written in other languages than Portuguese. A smaller number of complaints relate to the omission or incorrect use of information. Most of the cases are still under investigation by the competent authorities.

Sweden

The Consumer Agency receives approximately 200 complaints annually relating to claims; mostly these complaints concern dietary supplements and natural remedies. No further information is available. Out of approximately 200 complaints annually approximately 75 concern dietary supplements, approximately 40 slimming products and only a limited number concern nutritional/health claims for ordinary food products.

United Kingdom

The local Welsh Authorities on Trading Standards carried out a study to assess whether claims comply inter alia with the Food Labelling Regulations of 1996. This study would seem to imply that a number of claims are being made that, in the judgement of the local authorities, are unlawful.

Two other studies examining nutritional and health claims made on food products have been carried out by the Food Commission, which point to the need for further regulation to prevent consumers being misled.

In conclusion, whilst there is not a considerable body of evidence as statistics are concerned, nevertheless what statistical information exists clearly points to the fact that claims are being made, which are deemed misleading.

* * *

B. RECOMMENDATIONS

- Our overall conclusion is that to safeguard consumer protection, claims, whether they are nutritional, health or ethical, need to be better regulated at the EU level. The very large majority of the key stakeholders agree that solutions are to be found at the EU level and all look to the European Commission to propose legislation. In summary, our recommendations are as follows:

AMEND MISLEADING ADVERTISING DIRECTIVE No. 84/450	AMEND FOOD LABELLING DIRECTIVE No. 79/112	AMEND NUTRITIONAL LABELLING DIRECTIVE No. 90/496	OTHER LEGISLATIVE AND NON-MEASURES
a. Provide generic definition of a claim; b. Enlarge scope to cover all means of communication, including on-pack labelling; c. Introduce substantiation criteria for making claims; d. Introduce pre-clearance systems (generic and innovative list + pre-market advice / notification–due diligence; e. Post-clearance based on reversal of burden of proof + enforced penalties; f. Amendment to introduce similar system of out-of-Court settlements as in Directive 98/27; and g. CEN Standards (Voluntary Agreements).	a. Amend to provide definition of health claim; b. Amend Article 2 to allow certain types of health claims according to Codex: enhanced function claims and disease risk reduction claims; c. Scientific substantiation required; d. Generic list of allowed claims; and e. Innovative claims should require notification procedure.	a. Amend to introduce Codex guidelines for use if nutritional claims.	a. Definition of a foodstuff in a Framework Directive; and b. EU wide info campaign to educate consumers on the relationship between diet and health.

1. Horizontal Approach – Amending the misleading Advertising Directive

a. Definitions used in Misleading Advertising Directive

Currently there exists no legal definition of what a "claim" is. The Misleading Advertising Directive 84/450 does not directly refer to claims, but it is generally acknowledged that claims fall under its scope. In order to clarify this aspect of the Directive, we recommend to introduce a definition of claims, under Article 2 as point 4. Based on an analysis of the definitions used in national legislation and voluntary agreements, we suggest the following type of definition:

> "A claim is any direct or indirect statement, symbol, suggestion, implication or any other form of communication (including the brand name) that a good has particular characteristics relating to its origin, properties, effect, nature, method of production, processing, composition or any other quality".

b. Scope of the Misleading Advertising Directive

It is unclear whether the scope of the Misleading Advertising Directive encompasses all means of communication and, in particular, claims made on labelling (on-pack claims). All national legislation is based on the principle that a uniform set of rules should apply whatever the means of communication used.

We recommend that the Directive be amended so that it clearly applies to labelling. This could, for example, be done by introducing a provision which would state that the non-respect of labelling legislation should be considered misleading advertising. This would also be in line with the fact that, on a national level, misleading claims are often judged by the courts on the basis of the national rules on misleading advertising/unfair competition.

c. Substantiation of Claims

We would recommend introducing into the Misleading Advertising Directive (for example in the form of an Annex) a number of criteria that need to be fulfilled in view of the substantiation of claims. This seems in particular necessary, as an increased use of health claims can be expected over the coming years and, so far, criteria on the substantiation of health claims are only listed in voluntary instruments. Similarly, with regard to ethical claims, criteria are mostly set out in fair trade labelling schemes, but no criteria for substantiation of ethical claims are fixed by law.

In order to ensure a high level of consumer protection, it may be worth considering introducing the following criteria into a possible Annex of the Misleading Advertising Directive:

Claims must be:

- True and not misleading;
- Clear and understandable;

- Complete (indicate, for example, for health claims on food the dosage required, the effect over time, etc.);
- Precise and not using extrapolations/generalisations (eventually claims using words such as "implies", "suggests" etc. should be considered misleading);
- Objective (e.g. not evoke fears, or if testimonials are used must provide an objective image of the effects that a product claims to have);
- Substantiated, verifiable and documented;
- Supported by evidence if the claim is based on the composition/quality of the product.

We have limited the criteria of scientific evidence to those claims that are based on the composition/quality of the product for the following reasons:

- Firstly, it would evidently be possible to indicate that scientific evidence, as a criteria, should only apply to health claims. But in this case a definition of health claims would need to be inserted in the Misleading Advertising Directive. It can in our view, be questioned as to how far a definition of 'health claims' should not be left to 'vertical' legislation, i.e. Directive 79/112.

- Secondly, it is clear that certain ethical claims, such as 'produced without child labour', cannot be based on evidence, as they are not based on the composition of the product or the quality of the product.

- Thirdly, some ethical claims, notably the fair trade claims, for which some fair trade labelling schemes require the respect of certain environmental requirements, would, with this approach, fall under the obligation of sound evidence. This approach would also encompass nutritional and green claims.

- Fourthly, this solution also automatically eliminates any disputes as to whether specific claims fall under the chosen definition of health claims and whether for these specific claims scientific evidence was, therefore, needed or not.

d. Pre-Clearance

The following are possible options:

Pre-clearance for all claims

The advantage of a pre-clearance system for all claims is that it would ensure that in most cases only truthful and non-misleading claims are made. The disadvantages of such a pre-clearance system is that it is, from an administrative point of view, very burdensome (and raises the question of whether an EU level pre-clearance authority would need to be established, in order to avoid barriers to trade due to differing pre-clearance advice in the Member States). Furthermore, even under a pre-clearance system it cannot be excluded that some economic operators may make misleading claims. Finally, even pre-clearance from a government authority, does not give 100% assurance to an economic operator that a court may not find the claim unlawful.

Pre-clearance only for innovative claims (in this case a list of generic claims would need to be established)

A second option is to establish an EU list of generic claims for which no pre-clearance is needed, whilst for all other claims (new/innovative) pre-clearance is needed. The establishment of such a generic list could in our view only be done via Directive 79/112 on the Labelling of Foodstuffs. It also raises the question as to how far a list of generic ethical claims could be established and as to how far this could be added to the Misleading Advertising Directive.

Notification procedure (similar to the one set up under the Directive for Particular Nutritional Uses 89/398)

A third option would be to introduce a notification procedure such as the one under Directive 89/398 on Foodstuffs for Particular Nutritional Uses, whereby an operator has to notify the authorities of the placing on the market of a foodstuff for particular nutritional uses. The advantage for companies would be that they could put their product on the market immediately without having to await approval as in option a). The disadvantage of this system seems to be that it may prove difficult for national authorities, from an administrative point of view, to check all labels/claims used. This could partly be overcome if, at the same time, a generic list of claims was established for which no notification was required.

Assumption of due diligence in case of voluntary pre-clearance

A fourth option would be to encourage operators to submit, either in the framework of a voluntary agreement or in the framework of an administrative body, the claim that he/she wants to make for pre-clearance. Companies that follow this pre-clearance procedure could then be considered to have exercised due diligence. The courts may take this into account in the event of any legal challenge to the claims. The disadvantage of this solution is that in some Member States (Germany, Italy, Austria), due to the legal systems, courts may be tempted not to take such voluntary pre-clearance into account, in particular where such pre-clearance is carried out within the framework of a voluntary agreement to which the authorities are not a party. Such voluntary ageements could be considered as not being 'binding enough' to trigger an assumption of due diligence.

Reversal of the burden of proof, so that the maker of the claim bears the burden

A fifth possible way forward would be to counterbalance the absence of a pre-clearance system by reversing the burden of proof so that the maker of the claim would have to prove the non-misleading character and truthfulness of the claim. This seems to be a possible way forward, although the dissuasive effect of reversing the burden of proof would need to be examined in more detail. It has, nevertheless, the advantage that it would not impose any new burdens from an administrative point of view.

Weighing the advantages and disadvantages of all these options (for further details see section Comparative Analysis - Existence of Pre-Clearance and Post-Clearance), and in light of the diverging views of consumers and industry, the most viable solutions are in our view:

- a system of notification; and/or

- the model of assumption of due diligence in case of voluntary pre-clearance; and/or
- the reversal of the burden of proof.

All three options allow for increased consumer protection, whilst at the same time keeping the administrative burden within reasonable limits. Furthermore, all three options seem to be compatible with voluntary instruments on claims. In particular the model of voluntary pre-clearance, as well as the reversal of the burden of proof concept seem to be systems which could apply to all types of claims.

e. Post-Clearance

i. Burden of Proof

In those countries where the burden of proof lies with the plaintiff, there seem to exist problems in terms of bringing cases to the courts, notably as consumer associations do not have the means of paying an expert who could provide an opinion proving that a certain claim could not be scientifically proven. Therefore, we believe that a modification of the rules on burden of proof, as set out in the Misleading Advertising Directive, should take place.

Different options appear to be possible:

- To impose on the producer the obligation to provide all useful documentation and information so that the plaintiff can avail himself of concrete facts to prove his case.

- To make the producer bear the costs of an expert opinion under certain circumstances, e.g. on condition that the victim reimburses the costs in the event of failure.

- To make the reversal of the burden of proof dependant as to whether the producer has fulfilled certain criteria set out in an amended Directive on Misleading Advertising. The Directive could, for example, set out certain criteria applying to claims, in order to be considered non-misleading (for further details on this point see Substantiation of Claims below). If a manufacturer has fulfilled these criteria, the burden of proof would remain with the plaintiff.

- To reverse the burden of proof.

All arguments taken into account, the optimal solution is in our view a reversal of the burden of proof, i.e. it would be up to the maker of the claim to proove that his/her claim is non-misleading and truthful.

Nevertheless, a reversal of the burden of proof may be considered by some Member States as a profound intervention by the EU into its basic legal principles. In this case, we consider as second best option to make the reversal of the burden of proof dependant as to whether the producer has fulfilled certain criteria set out in an amended Directive on Misleading Advertising, whilst at the same time requiring the

maker of the claim to provide all useful documentation and information so that the plaintiff can avail himself of concrete facts to prove his case.

ii. Applicable Penalties

In order to guarantee the same level of consumer protection in all Member States with regard to the sanctioning of misleading claims, one option could be to introduce a provision into the Misleading Advertising Directive, requiring Member States to introduce effective and dissuasive sanctions against the use of misleading claims.

f. Out-of-Court Settlement

Since, in a number of Member States, disputes are often being resolved in an informal way outside the courts, it would be interesting to see if this could be introduced in all Member States. For example, along the lines of a system as foreseen under Directive 98/27 on Injunctions for the Protection of Consumer Interests. The Directive foresees that the party that intends to seek an injunction can only start this procedure if it has tried to achieve the cessation of the infringement in consultation with either the defendant, or with both the defendant and a qualified entity (i.e. public bodies and organisations whose purpose it is to protect the collective interests of consumers).

g. Technical Standards for Claims

The question can be raised as to how far the proliferation of national voluntary agreements (in particular in the area of health claims) does not lead to different levels of consumer protection within the EU, as well as to the creation of new barriers to trade. Whilst one could argue for a European voluntary agreement for example in the area of health claims or ethical claims, the problem is that:

- The means of surveillance and sanctions of voluntary agreements are rather limited;
- Voluntary agreements may not work in some countries for legal reasons (notably Italy and Germany); and
- If not all relevant parties sign up to a voluntary agreement, it will lack broad social legitimization.

One could, therefore, argue that legislation might be the right way forward.

Another possibility would be to model consumer protection in the area of claims on the new approach in harmonisation used for technical legislation, i.e. EU legislation only establishes the general principles and essential requirements. For the technical details, reference is made to standards due to be established by standardisation institutes (e.g. CEN), following a mandate from the Commission. As in the technical area under this scenario, if standards are met, there would be a presumption that the claims used are in conformity with the essential requirements for claims as set out in an amended Misleading Advertising Directive.

The voluntary instruments that have been developed at national level could be used as a source of inspiration and a link could be established whereby, for example, certain

voluntary instruments could be certified as being in conformity with the standards that have been developed. In this way, national voluntary instruments that work well could continue to exist (although some amendments may be needed).

The advantage of this approach is that standardisation is probably an easier way forward than exhaustive legislation and, on the other hand, it has a greater legal authority (in particular if developed under Commission surveillance and with a clear mandate) than voluntary instruments.

It is clear that the standardisation approach will need to resolve a number of issues, in order to become a viable and functioning option:

- Funds will need to be made available by the EU for setting standards in the area of claims;
- An 'education process' amongst the standards institutes will be necessary to switch their culture from being essentially focused on technical/scientific aspects to the less precise and clear cut area of claims (standardisation institutes have already some experience in this area, e.g. ISO standard 14021 on green claims); and
- Ways and means will have to be found to enable consumer associations to participate adequately and equally with industry in the standardisation work.

2. Vertical Legislation – Amending 79/112 and 90/496

A number of proposals are made, which will need to be addressed under the two vertical Directives regulating nutritional labelling (90/496) and food labelling (79/112).

a. Revision of 79/112

- A definition of health claims is needed, in order to overcome, on the one hand, currently existing barriers to trade and, on the other, to address the question of the use of enhanced function and disease risk reduction claims. This needs to be addressed, in our view, via the Food Labelling Directive (79/112).

- It is clear, that for the use of health claims, more detailed criteria should be set with regard to scientific substantiation. This has been done in a number of voluntary codes on health claims. In our view, such criteria would need to be addressed in another legal framework, e.g. via Directive 79/112.

- The Codex Alimentarius draft April 1999 guidelines on the use of enhanced function claims and reduction of disease risk claims (even if they go further than the allowed scope of Directive 79/112) have received wide support from both industry and Member States authorities and even from certain consumer groups. Hence, an amendment to 79/112 and, in particular, to Article 2, (and Directive 65/65) to allow these types of claims may be considered.

- The consideration of a clear set of criteria under which a health claim can be made. For example, a positive list of generic claims.

b. Nutritional labelling (90/496)

This Directive could be amended to include, in an Annex, the Codex guidelines for use of nutritional claims, which define four different types of claims (nutrient content, comparative, nutrient function and claims related to dietary guidelines of healthy diets to provide additional clarity, as well as ensuring that nutrient content claims are clearly defined in terms of the quantitative level of the nutrient present, be consistent between products, and be meaningful to consumers.

3. Other Measures

a. Food Law Framework Directive

The definition of a foodstuff is much needed and should come in a Framework Directive on food law. This would have the purpose of clearly defining what is and what is not a foodstuff; thereby reducing the problem of borderline cases with pharmaceutical products as defined under Directive 65/65.

b. Information Campaign

Consumer organisations wish to see the EU setting-up an information campaign to educate and inform consumers on the link between diet and health.

c. Ethical Labelling

A definition of ethical claims should be addressed in any future legislation on ethical labelling, if such legislation is to be considered necessary in the medium term.

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III. COMPARATIVE ANALYSIS

A. DEFINITIONS, LEGISLATION, POLICY DEVELOPMENTS AND STAKEHOLDERS' POSITIONS

1. Comments

- In the following we examine (i) the definitions given to all three types of claim; (ii) the legislation in place and how it differs to that of the EU Directives; and (iii) the policy developments and positions of the major stakeholders, namely government/responsible Ministries, consumer organisations and industry (to a very large degree the food and beverage industry, but also retailers).

A. Definitions and Legislation

- The first point to make is that there is no legal definition of what a "claim" is at either national or EU level. However, Codex Alimentarius defines a claim for the food sector. The EU Misleading Advertising Directive 84/450 does not directly refer to claims, but it is generally acknowledged that claims fall under its scope. The Misleading Advertising Directive can be seen as providing for certain restrictions and prohibitions, as it defines in Article 2 (2) misleading advertising as:

  > "…any advertising which in any way, including its presentation, deceives or is likely to deceive the persons to whom it is addressed or whom it reaches and which, by reason of its deceptive nature, is likely to affect their economic behaviour or which, for those reasons, injures or is likely to injure a competitor"

a. Nutritional Claims

- Nutritional claims are defined in law, both at EU and national level, in compliance with Directive 90/496 on the Nutrition Labelling for Foodstuffs, article 1, para. 4 (b) as:

  > "any representation and any advertising message which states, suggests or implies that a foodstuff has particular nutrition properties due to the energy (calorific value) it provides; provides at a reduced or increased rate or; does not provide; and/or due to the nutrients it contains; contains in reduced or increased proportions or; does not contain. A reference to qualities or quantities of a nutrient does not constitute a nutrition claim in so far as it is required by legislation".

- All definitions are by and large the same and follow the Codex guidelines, except for Ireland, Germany and The Netherlands, which are more restrictive.

b. Health Claims

- Health claims are defined in terms of what they cannot do, establishing a prohibition for certain types of health-related claims. As such, there is no legal definition of what is a health claim. Due to the increasing unclarity of Directive 79/112 on the Labelling Presentation and Advertising of Foodstuffs and specifically Article 2, paragraph1 (b) codified version, which reads :

  "1. The labelling and methods used must not:
  […]
  (b) subject to Community provisions applicable to natural mineral waters and foodstuffs for particular nutritional uses, attribute to any foodstuff the property of preventing, treating or curing a human disease, or refer to such properties."

  Health claims are interpreted differently (either a more liberal regime such as in the UK or a restrictive/to the letter of the law such as in Germany and Italy) throughout the EU.

- There are also a number of developments, which have added to the debate as to the definition of health claims:
  - Certain Member States, such as the UK, have an unofficial definition which is commonly accepted;
  - the more liberal definitions coming from the US and Canada;
  - the recent work in the Codex Alimentarius, which has defined a health claim and come up with draft guidelines on allowed claims (enhanced function claims and reduction of disease risk claims, the latter going further than the allowed scope of Directive 79/112) and their specific definitions; and
  - the various voluntary agreements/codes of practice in several Member States (Belgium, The Netherlands, Spain, Sweden, and UK) have developed definitions of a health claim, which are usually broader in its scope than Directive 79/112.

- As to the variations with regard to the definition of a health claim, there are widespread differences. Six countries have a more restrictive approach, namely Austria, Belgium, Germany, Italy, Luxembourg, Portugal, whilst three countries have a more liberal approach namely Finland, France, UK and the other seven tend to take a middle ground between the two.

c. Ethical Claims

- With regard to ethical claims, there is no direct legislation or legal definition in any of the Member States. Nevertheless, each Member State has legislation which indirectly applies to ethical claims, most often due to national implementation of the EU Directive on Misleading Advertising.

- Ethical claims – whatever they cover exactly (there are differing views but in essence they cover labour-related working conditions) are a fairly new phenomenon/type of labelling, which have only appeared on products in the last few years.

B. Policy Developments and the Positions of the Major Stakeholders

a. Nutritional Claims

- Interestingly, policy thinking and developments in the Member States clearly demonstrate that on nutritional claims, as a whole, most stakeholders are generally satisfied with the current legislative environment. It has to be noted that the UK consumer organisations are the exception as they are seeking further restrictive rules, wishing to see criteria for absolute and relative claims, a full supporting nutritional panel and a set of standard criteria for healthy eating symbols.

- The key development is the discussions on the Codex Guidelines for use of nutrition claims, which define four different types of claims (nutrient content, comparative, nutrient function and claims related to dietary guidelines of healthy diets). There is quite a large consensus that these should be annexed to the Nutritional Labelling Directive.

- There are also three countries where voluntary codes/guidelines have been set-up to provide further information to industry, namely in Denmark, Finland, and the UK, such as the UK FAC guidelines, perhaps demonstrating the need to better assist industry in order to provide consumers with better/legal/truthful information. Another example is the Co-operative Wholesale Society (CWS) which has developed its own code of practice for labelling of pre-packed foods for both nutritional and health claims. The views of the CWS are that the lack of detailed provisions could lead to the potential of misleading consumers.

b. Health Claims

- Health claims, without a doubt, pose the biggest problem and the major challenge. The various and numerous developments taking place throughout Europe are clearly indicative of the need to establish a better regulatory framework. The Codex Alimentarius draft April 1999 guidelines recommending the use of enhanced function claims and reduction of disease risk claims have received wide support from both industry and Member States authorities and even from certain consumer groups. Also, the developments across the Atlantic in both the US and Canada are demonstrative of the liberal approach to health claims gaining ground.

- The voluntary codes/agreements set-up in Sweden, Spain, The Netherlands (already in operation) and in Belgium and in the UK (both expected to become operational in 2000) and the EU level one developed by the CIAA (adopted September 1999) is a clear demonstration of how regulators, industry and, to a large extent, consumers have come together to pave the way forward. The definitions, criteria, verification systems established in these voluntary codes/agreements should be viewed as a blue print for what should be done at EU level.

- Below, we list the key demands of the stakeholders. Many of these will of course form the basis for our recommendations. Please note that some issues, such as the voluntary codes/agreements, the verification systems (pre-and post-clearance, burden of proof, sanctions), means of communications, case law, barriers to trade,

consumer protection are further detailed in the next comparative sections and, therefore, this section must be seen in the overall context:

i. Regulators

- Virtually all Member States (perhaps Spain and Belgium are somewhat more reticent and possibly The Netherlands does not see a great need) agree that it should be at the EU level that the problems surrounding health claims are resolved;
- The large majority of Member States have expressed the need to amend Directive 79/112 in order to meet current requirements;
- They consider Codex draft guidelines as the way forward in order to introduce a more liberal regime;
- They accept that perhaps, a definition of a foodstuff should be elaborated to avoid the problem of borderline cases;
- They realise that they need to consider:
  * allowing enhanced function and disease risk reductions claims;
  * drawing-up a positive list of generic claims;
  * introducing pre-clearance and/or introducing pre-clearance for innovative claims; and
  * reviewing the criteria to establish what type of claim can be made.
- They view the voluntary codes/agreements as a step in the right direction but ultimately wish to see legislation in place.

ii. Consumer Organisations

- They are calling for action, preferably at the EU level, although this does not mean that nothing should be done at national level;
- They prefer criteria for substantiation to be developed as opposed to a positive or negative list of health claims;
- They want pre-clearance for all claims;
- They want the supervision/control of claims once on the market to be tightened to guarantee consumer protection;
- They want the burden of proof to lie with the maker of the claim in order to allow easier, cheaper prosecution;
- They would like to see an amendment to the Misleading Advertising Directive to include distance selling and electronic commerce; and
- They wish to see the EU setting-up an information campaign to educate and inform consumers on the link between diet and health.

iii. Industry

- Industry is of the view that the EU is the best level to create a clear regulatory environment. Whilst ideally industry would like to see self-regulation as the way forward, industry is realistic that a code might not be able to work in each country (Italy and Germany for legal reasons) and the fact that regulators and consumers favour legislation.

- In addition, industry is calling for:

- The introduction of a more liberal regime;
- An amendment to 79/112 (and Directive 65/65), and Article 2 in particular to allow new types of claims, in particular disease risk reduction claims and enhanced function claims;
- The consideration of a clear set of criteria under which a claim can be made;
- No pre-clearance, but well defined post clearance verifications;
- A voluntary code/agreement to create the necessary framework (German and Italian industry would probably oppose this).

- Retailers and other industry-related interests favour only enhanced function claims and call for criteria to be drawn-up under which conditions a claim can be made (a positive list is possible).

- The Advertising industry calls for self-regulation.

c. <u>Ethical Claims</u>

- With regard to ethical claims, whilst there is no real perceived problem, a large number of stakeholders (retailers are perhaps overall against) tend to agree that they should be regulated in order to avoid problems and guarantee consumer protection in the future, given that the expectation is that they will proliferate. The European Parliament has called for a social label, together with a code of conduct for European businesses that should comprise existing minimum applicable international standards.

- Only two countries, Belgian and Italy, are drafting legislation. In Belgium, there is a consensus that a regulatory framework is required, which has led to two proposals: one for the promotion of socially responsible production with a label (ILO standards) and one for adding labelling/advertising provisions with an ethical notion to the unfair competition and consumer information law. In Italy, the Parliament is adopting a law on the certification of social conformity (and label) of products produced without the use of child labour.

- As with health claims, voluntary agreements/codes of conduct are being set-up for ethical claims. The most well known one is the Fairtrade Labelling Organisations International (FLO), which does not have a claim as such but a fairtrade label, which could be/is associated by consumers with certain ethical standards. Whilst there is no question of lack of consumer protection, there is nevertheless the view that an independent verification system should be carried out.

- In addition to Belgium and Italy, four other Member States (Denmark, France, Portugal, and Sweden) have seen developments signalling a call to regulate ethical claims in some form. The other nine Member States are not against doing anything; they simply have not considered the issue and, hence, have no position.

- On the whole consumer organisations have not developed a defined viewpoint/position on ethical claims. Suffice to say that they want them to be regulated, like any other claim, via the right channels. By contrast, as a whole, industry do not perceive ethical claims to be an issue, as their use is limited.

In the following, we provide, firstly, a table which gives a comparative analysis of the definitions used and legislation in place and, secondly, a table which gives an overview of policy developments and the stakeholders' positions.

2.a) Comparative Analysis: Definitions and Legislation

Country	Nutritional Claims	Health Claims	Ethical Claims
EU	**As defined in Directive 90/496**	**EU Directive 79/112 explains what a health claim must not do**	**No definition or specific legislation**
Austria	Clear definition and direct transposition of EU law. Although satisfied with current rules, consideration is being given to a revision to include certain substances such as potassium.	Implemented Directive 79/112 but **stricter** as it forbids references to physiological effects. June 1999 Enactment provides list of which claims are allowed to provide clearer guidelines. **Does not allow disease risk reduction claims and enhanced function claims are limited.**	No definition or specific legislation.
Belgium	Nutritional claim definition is a literal translation of EU definition and transposes Directive 90/496.	No definition for health claims, but restrictions not to use them are in place, although different to Directive 79/112. **Disease risk reduction claims are banned. Generally viewed as too restrictive**.	No definition or specific legislation, but an ethical definition has been proposed in draft law.
Denmark	Same as Directive 90/496.	Very similar to Directive 79/112.	No definition or specific legislation.
Finland	Same as Directive 90/496.	In line with Directive 79/112 but **allows enhanced function claims** as defined in Codex.	No definition or specific legislation.
France	Same as Directive 90/496.	In line with Directive 79/112. No definition, but **accept Codex definition**	No definition or specific legislation.
Germany	Very similar to Directive 90/496, but does not allow claims on the absence of certain nutrients.	No definition but implemented word for word 79/112 but has extended the prohibitions, establishing a **more restrictive interpretation**. Could allow certain enhanced function claims (as defined by Codex) but does not permit diseases risk reduction claims.	No definition or specific legislation.
Greece	Conforms to Directive 90/496.	No definition, but Code provides the notion of health claims in terms of prohibitions and respects, word for word, Article 2 of 79/112.	No definition or specific legislation.
Ireland	Conforms to EU law, but stricter than Codex as claims related to dietary guidelines or healthy diets are not allowed.	Conforms to EU 79/112, word for word.	No definition or specific legislation.
Italy	Definition identical to Directive 90/496.	No definition but conforms to EU 79/112, although a more **restrictive approach** is adopted. They do not accept disease risk reduction claims and enhanced function claims are very limited.	No definition or specific legislation.
Luxembourg	Definition identical to Directive 90/496.	Health claims are banned. Conforms to EU 79/112, although a more **restrictive approach** is adopted. **They do not accept disease risk reduction claims and enhanced function claims are very limited.**	No definition or specific legislation.

Country	Nutritional Claims	Health Claims	Ethical Claims
Netherlands	Definition same as EU 90/496, but somewhat more restrictive.	No definition but banned under Directive 79/112. Definition identical to EU.	No definition or specific legislation.
Portugal	Definition same as Directive 90/496.	No definition and banned under and conforms to Directive 79/112, although a more **restrictive approach** is adopted. **They do not accept disease risk reduction claims and enhanced function claims are very limited**.	No definition or specific legislation.
Spain	Definition same as EU 90/496.	No definition and banned under and conforms to Directive 79/112	No definition or specific legislation.
Sweden	Definition same as Directive 90/496 + Keyhole trademark symbol to define certain products.	No definition and banned under and conforms to Directive 79/112. Swedish Food Act defines foodstuff.	No definition or specific legislation.
UK	Definition same as Directive 90/496.	No definition and banned under and conforms to Directive 79/112, although there is a generally accepted definition.	No definition or specific legislation.
US		List of 10 authorised health claims. Allows structure and function claims (same as the European term enhanced function claim).	No definition or specific legislation.
Canada	Definition of a nutrient content claim (and comparative claims) are the same as Codex but not legally enforceable	No definition but a difference is made between therapeutic and risk reduction claims which are banned and structure, and function claims, which are allowed, but there is a legislative framework.	No definition or specific legislation.

2.b) Comparative Table: Policy Developments and Stakeholders' Positions

Country	Nutritional Claims	Health Claims	Ethical Claims
EU	Discussion about Codex Guidelines for use of nutritional claims, which define 4 different types of claims (nutrient content, comparative, nutrient function and claims related to dietary guidelines of healthy diets, to be annexed to Nutritional Labelling Directive.	Draft Codex Guidelines recommend the use of enhanced function claims and reduction of disease risk claims. European Parliament backs this position as does the food industry at large, calling for an amendment to 79/112 (and Directive 65/65) and Article 2 to allow disease risk reduction claims. Retailers and other industry-related interests favour only enhanced function claims and call for criteria to be drawn-up under which conditions a claim can be made (a positive list is possible). Consumers want strict legislation, no positive or negative list, but instead criteria to ensure that only true and non-misleading claims are made. The advertising industry calls for self-regulation.	European Parliament called for Social Label to ensure existing minimum applicable international standards. DG development is finalising a Communication on Fair Trade. Eurocommerce is against legislation, as they will not often be used, the difficulty of ensuring complete veracity and market will regulate false ethical claims itself. Not an issue for BEUC.
Austria	**X** No need for revision, except for allowing other substances not currently listed.	Authorities concede that certain health claims should be allowed, combined with pre-clearance. This is backed-up by industry which views legislation as far too strict (even against EU law) and call for physiological claims to be allowed. Consumers are, however, opposed to health claims and seek pre-clearance.	**X** Nothing envisaged.
Belgium	**X** No plans to change the law.	Authorities accept that following the voluntary code on health claims, there is a need to revise the law to accept disease risk reduction claims. The industry views current rules as too restrictive, calling for revision as above as well as calling for the voluntary code to be rolled-out across Europe. Consumers are, however, sceptical.	Consensus that a regulatory framework is required – two proposals on the table: one for the promotion of socially responsible production with a label (ILO standards) and one for adding labelling/advertising provisions with an ethical notion to the unfair competition and consumer information law. NGOs are the driving force
Denmark	Danish Food Directorate accepts need to allow nutrient function claims in accordance with Codex. Under voluntary agreement, the S-Label developed to indicate products low in fat or sugar.	Danish Government accepts need to have wider application of health claims to accept reduction of disease risk claims but not enhanced function claims (physiological claims) and accepts US/Swedish model that any claim relating to a specific food product is placed in the context of the total diet and favours EU action and measure.	Government calling for effective definition and new labelling system at EU level.

Country	Nutritional Claims	Health Claims	Ethical Claims
Finland	**X** Stakeholders agree that there is no need to make changes to the law, but are working on guidelines for the use of nutritional declarations and nutritional claims due in Autumn 1999.	Government and industry favour a more liberal regime as per Codex, and wish for EU framework accepting enhanced function claims. Government favours explicit list of acceptable and prohibited health claims. Industry is seeking acceptance of disease reduction claims but NFA considers that an amendment is needed of Directive 79/112. Consumers fear introduction of health specific claims for products and, therefore, call for the Swedish approach and question lack of supervision and control of health claims.	**X** Government has not considered ethical claims nor does it plan to. However, the Consumer Agency will make it a priority in 2000.
France	**X** There is no indication that any changes should be made.	June 1998 Conseil National de L'Alimentation Opinion (backbone of French thinking) on health claims elaborates 12 conditions to be met in order to accept the development of health claims. The first bans therapeutic claims, but allows disease reduction claims, claims suggesting a contribution to the general health condition and nutritional and functional claims. Most stakeholders want EU framework. Industry is dissatisfied with the visa PP procedure for authorising health claims and consumers want the Misleading Advertising Directive to be extended to distance selling and electronic commerce.	The authorities view the need to establish framework at either EU or international level, as they do not see themselves as competent. The campaign "de l'éthique sur l'étiquette" has considerably heightened awareness of the issue.
Germany	**X** Current legislation is deemed satisfactory and no initiatives are planned, except for the review of the 15% RDA value.	Authorities view current situation as satisfactory, but due to the problem of borderline cases, the EU needs to define "foodstuff" before legislating by amending Directive 79/112. They could envisage disease risk reduction claims, but would intensify borderline problems with pharmaceuticals. Consumers believe EU legislation is necessary due to increase of functional foods, food supplements and probiotic foodstuffs. Industry wishes to be able to make disease risk reduction claims and believe the best way forward is to amend Directive 79/112. They also see the need to define what a foodstuff is. Voluntary agreements are not perceived as a viable way to address the issue in Germany.	**X** The authorities do not have a position, consumers wish to see the burden of proof to be shifted to the manufacturer for all claims and industry do not see the need to legislate.
Greece	**X** No changes planned.	All stakeholders favour EU action to resolve problems of consumer protection, and borderline cases. Industry favours the CIAA Voluntary Code and consumers generally believe that more protection is required with the proliferation of health claims. The advertising industry is against any EU involvement or amendment to the Misleading Advertising Directive and opt instead for self-regulation.	**X** No developments to speak of.

Country	Nutritional Claims	Health Claims	Ethical Claims
Ireland	**X** Legislation is working well and no need for review. Industry is, however, calling for clarification as to what types of claims can be made.	The FSAI views that the EU should clarify borderline cases, making reference to Directive 65/65, should issue a positive list of claims (based on sound science such as the US FDA), wants to see pre-vetting/clearance and the burden of proof to be placed on the maker of the claim. Industry seeks clarification, positive/generic list of allowed claims and promotes self-regulation along the lines of the UK JHCI. Consumers want the EU to launch information campaign to enhance consumer protection and awareness.	**X** No developments to speak of. Although consensus that independent checks should be considered in the future with the proliferation of such claims.
Italy	**X** The authorities are not satisfied with the current law although they would like further preventive measures to be introduced. Industry is satisfied.	**X** Stakeholders do not see the need to change the law, although if changes are to be made it should be at EU level. They would also consider pre-clearance. Industry favours amending Directive 79/112 to liberalise the regulatory framework and is opposed to pre-clearance.	The Italian Parliament is adopting a law on the certification of social conformity (and label) of products produced without the use of child labour. Industry is opposed.
Luxembourg	**X** No legislative changes are foreseen.	**X** No legislative change is foreseen, although stakeholders generally agree that the development of a sound regulatory environment should be established at EU level. Consumers are in favour of control at EU level.	**X** No developments to speak of.
Netherlands	**X** Current legislation is satisfactory and stakeholders see no need for change. Some policy developments relating to different types of fats.	**X** At home, all stakeholders view current legislation as satisfactory, supporting self-regulation as in the case of the voluntary codes. The stakeholders accept that changes are needed to sort out the problem of borderline cases, best resolved at EU level. Industry is calling for the acceptance of disease reduction claims and would like to see in place an EU voluntary code to create an appropriate framework to operate in. Consumers wish for the problem of borderline cases to be resolved at EU level, as well as for the EU to assist Member States in providing guidance on the substantiation of claims.	**X** No developments to report and no defined positions except that industry prefers self-regulation.
Portugal	**X** All stakeholders view current legislation as satisfactory.	**X** No legislative or policy changes are planned. There is no debate on the issue. Industry would like to see a more liberal regime and is looking to the EU level to create a proper regulatory environment. Consumers favour clearly defined rules for substantiating claims.	Consumers are calling for the introduction of a mechanism to supervise the use of ethical claims, either via legislation or code of conduct.
Spain	**X** Stakeholders see no need to amend legislation, deemed satisfactory, although open to extending the list of allowable claims in the event of new nutrients.	**X** Whilst stakeholders are not planning to amend legislation, there is a need to accommodate new types of health claims. Government might not want EU involvement. Industry has its voluntary code and supports CIAA Code in combination with Codex work. Consumers welcome EU initiative.	**X** No real interest from authorities and consumers would like to see EU framework.

Country	Nutritional Claims	Health Claims	Ethical Claims
Sweden	**X** Stakeholders are satisfied with current legislation.	Stakeholders favour EU based regulatory framework. Sweden is considering to launch health claim initiative during its Presidency of the EU in 2001. Stakeholders all favour voluntary code (defines a health claim) and now being amended to include product-specific physiological claims.	Recent government study raised issue of ethical labelling, recommending EU level co-operation to ensure that consumers avoid products, which are manufactured by companies, which behave unethically.
UK	**X** Government does not perceive a need to review legislation, although FAC guidelines on use are regularly updated. However, consumer organisations are seeking further restrictive rules, wishing to see criteria for absolute and relative claims, a full supporting nutritional panel and a set of standard criteria for healthy eating symbols. Industry seems to indicate that regular clarification updates are necessary. Also, CWS has set-up a Code for consumer labelling clarity.	All stakeholders favour the Joint Health Claim Initiative, although consumers and government eventually want an EU regulatory framework to harmonise the use of health claims. Consumers also still prefer pre-market clearance. Industry favours the JHCI, does not accept pre-clearance but accepts burden of proof and wishes to see an amendment to Directive 79/112 to allow disease risk reduction claims and to take onboard the latest Codex draft guidelines on health claims. The organisations that regulate the means of communication are firmly opposed to EU legislation, as the system appears to work correctly.	**X** No real position and no comprehensive approach by either stakeholders.
US	Current regulatory system working well.	Current regulatory system working well. There is, however, the concern that allowing industry greater flexibility to make claims with no prior approval, will result in an increase of questionable claims. This and the Internet may put questionable claims beyond the effective reach of the regulatory authorities.	**X** No developments.
Canada	Health Canada would like to regulate all nutrient content claims, but industry is opposed seeking non-regulatory measures. Compositional criteria are under review for nutrient content claims.	The legislative framework is being modified to introduce the US 10 generic risk reduction claims as well, as in the future, to adopt standards of evidence and a guidance document for the submission of innovative risk reduction claims, as favoured by industry. Consumers, to a large extent, agree with the developments, as it will improve the information to the consumer.	**X** Federal authorities have no position, they are not part of the current review. Consumers and industry are not focused on them**.**

X = No need to change current regulatory framework
= General need to change current regulatory framework

3. Recommendations

- From the above analysis, it should be considered whether or not a definition needs to be adopted for:
  - a foodstuff;
  - a claim;
  - a health claim; and
  - eventually, in the medium term for ethical claims, once these are being more used.

- We would recommend that a definition of a claim be made and included in the Misleading Advertising Directive, based on various definitions currently in existence relating to claims. We would propose the following definition:

  > "A claim is any direct or indirect statement, symbol, suggestion, implication or any other form of communication (including the brand name) that a good has particular characteristics relating to its origin, properties, nature, method of production, processing, composition or any other quality".

- A definition of health claims should in our view be addressed via the Food Labelling Directive 79/112. Equally, a definition of ethical claims should be addressed in any future legislation on ethical labelling, if this is to be considered necessary.

- In terms of legislation, we consider that a number of horizontal issues (such as burden of proof; pre-clearance/post-clearance) should be addressed via the Misleading Advertising Directive. Nevertheless, there are a number of more vertical issues (e.g. detailed criteria for scientific substantiation of health claims), where solutions have to come via the "vertical" Directives on nutritional labelling (90/496) and on food labelling (79/112).

- We consider notably, that the use of enhanced function claims, as well as disease risk reduction claims needs to be addressed in the coming years via Directive 79/112 on food labelling.

B. CONSUMER PROTECTION

1. Comment

In a majority of European countries, protection of the consumer appears as a major concern when it comes to setting rules with regard to claims. Most legislation is specifically designed to protect health and safety of the consumer and to avoid the use of false, exaggerated or misleading claims. However, it seems that some national legislation does not always provide a sufficient degree of consumer protection.

A potential or actual lack of consumer protection was indeed reported in a number of European countries. Not all types of claims are equally concerned, however, and a differentiation needs to be made between nutritional claims, health claims and ethical claims. Whereas nutritional and ethical claims pose no major problem in terms of consumer protection, the use of health claims appears problematic.

It was reported that, in countries such as Austria, Belgium, France, Greece, Portugal, UK, health claims are still made which might mislead the consumer. This problem is due to various factors:

- insufficient legal protection;
- absence of substantiation criteria or difficulty in defining such criteria;
- difficulty in the implementation of existing rules (because of a lack of resources or the overall weakness of the surveillance authority, for instance);
- growing number of borderline products, which are difficult to classify as either foodstuffs or drugs;
- claims are made in the absence of a general dietary context;
- difficulty in differentiating between health claims and medicinal claims; and
- increasing variety of complex claims.

It should be noted that the issue of consumer protection is understood differently by the various interested parties. Consumers usually consider that if there is room for a misleading claim to be made, a consumer protection problem exists. National authorities tend to believe that there is no such problem if the claim can be withdrawn, because then the damage is limited.

A majority of stakeholders in the Member States, including stakeholders in France, the United Kingdom, Ireland, Greece, Spain, Luxembourg, The Netherlands and Italy advocate the regulation of health claims by the European Union in order to ensure a higher level of consumer protection.

In the following table we provide a comparative overview of the consumer protection issues that have been perceived with regard to nutritional, health and ethical claims.

See TABLE on page 47

2. Comparative Table: Consumer Protection

no particular problem
problem
important problem

Country	Nutritional Claims	Health Claims	Ethical Claims	Comments
EU			×	All European consumer groups consider that legislation on health claims is needed because of the increasing number of claims made and the growing risk of misleading claims.
Austria	×		×	Austrian authorities consider the authorisation system which applies to health claims as an effective means of consumer protection. The Austrian consumer association stresses that, despite the authorisation procedure, there are still cases in which misleading claims are made.
Belgium	×		×	The Federal consumer association points out the difficulty for consumers to interpret health claims. As a consequence, health claims often appear misleading in Belgium.
Denmark	×	×	×	There are no consumer protection problems with regard to health claims because of the restrictive nature of Danish legislation.
Finland	×	×	×	No consumer protection problems were reported by the Finnish stakeholders.
France	×		×	Following consultations with all interested parties, the *Conseil National de l'Alimentation* (CNA) drew up a list of strict conditions for the use of health claims. No action was taken since France seeks a broader European approach to the problem. Consumer organisations consider that the protections provided by law against misleading health claims is insufficient. The industry considers that legislation on advertising and the prohibition of claims relating to specific diseases are sufficient to protect the consumers
Germany	×		×	The main consumer association reports problems of consumer protection, particularly with regard to functional foods, food supplements and probiotic foods. This situation is all the more preoccupying that these types of products very often bear claims. The German Ministry of Health considers that German legislation is sufficient in terms of consumer protection. However, it reports problems with selective claims (made out of context) and more subtle forms of claims such as sponsoring of health-related television programmes. The Centre for Fight against Unlawful Competition believes that German legislation provides for adequate consumer protection but admits that the category of food supplements is problematic.

Country	Nutritional Claims	Health Claims	Ethical Claims	Comments
Greece	×		×	Public authorities and consumer associations report a general lack of consumer protection in Greece, mainly due to the weakness of the surveillance system. Consequently, public authorities would like to see all issues relating to claims regulated at the EU level.
Ireland	×		×	Both the Irish government and the Consumer Association of Ireland indicate that there is a definite lack of consumer awareness about claims. In spite of the prohibition of health claims, some of the claims made may constitute health claims and even be misleading. Borderline products are particularly problematic. According to the national authorities, the Advertising Standard Authority of Ireland (clearance body) sometimes allows claims that are prohibited.
Italy	×	×	×	No major problem regarding health claims because of the restrictive nature of Italian legislation.
Luxembourg	×		×	The Luxembourg administration does not have the resources to control every product entering its market and hence fear that the protection of consumers might not always be guaranteed. Similarly, judicial redress procedures are difficult to use in Luxembourg, since in most cases the producer of the product does not operate on the territory of Luxembourg
Netherlands	×	×	×	There is no significant problem regarding consumer protection in The Netherlands. However, stakeholders point to potential problems because of borderline cases between positive health claims and medical claims. Difficulty in proving whether health claims are misleading or not. Agreement of most interested parties that problem of health claims should be coordinated at EU level.
Portugal	×		×	Portuguese consumer associations stress that existing legislation on health claims does not offer sufficient protection to the consumers, mainly due to the absence of clearly defined rules for substantiating them.
Spain	×		×	Spanish authorities consider borderline products as problematic for consumer protection.
Sweden	×	×	×	No significant problems regarding consumer protection were reported, as policy thinking is primarily based on the need to protect the consumer.
UK			×	Consumer associations provide examples of lack of consumer protection from nutritional claims. Both the British government and consumer associations report a lack of consumer protection with regard to health claims.
United States			×	Consumer groups consider that the abolition of the prior authorisation system for nutritional and health claims in 1994 has led to a decrease in the level of consumer protection.
Canada	×	×	×	No major problems regarding consumer protection were reported.

3. Recommendations

Whilst there is a perceived consumer protection problem, not all types of claims are equally concerned. The main problems are perceived in the case of health claims. Nevertheless, the problems associated with the use of health claims are often of a horizontal nature, i.e. burden of proof, pre-clearance vs. post-clearance etc.

These horizontal problems can ideally be addressed via adequate amendments to the Misleading Advertising Directive. Also, as increased use of ethical claims may be expected in the future, this would allow the development of a legal framework, which already takes future developments into account, instead of legislation on a reactive basis.

Clearly, there are a number of vertical issues, which we consider cannot be addressed via an amendment to the Misleading Advertising Directive. These issues will be developed further in the following sections of the comparative analysis.

C. BARRIERS TO TRADE

1. Comment

Barriers to trade have essentially been reported with regard to health claims. None of the stakeholders mentioned barriers to trade with regard to ethical claims. As to nutritional claims, some very small problems were reported, as sometimes the reference values for making a nutritional claim differ between Member States.

As to the barriers to trade in the area of health claims, these were mainly reported by industry. It is interesting to note that barriers to trade were mentioned in either those countries that have a very strict interpretation of health claims (e.g. Austria, Italy, etc.) and/or those countries that have a pre-clearance system in place (e.g. Austria, Belgium, France).

Furthermore, some barriers to trade were reported by the authorities, where food supplements being imported from other countries are often categorised as medicinal products (e.g. Germany, UK).

Potential future barriers to trade have also been reported with regard to voluntary agreements on health claims and, in particular, with regard to the UK Joint Health Claims Initiative. As this initiative is likely to allow liberal health claims, it may lead to barriers to trade with Ireland.

In general, and quite logically, barriers to trade seem to appear between countries that share the same language, such as Austria and Germany, or the Flemish part of Belgium and The Netherlands.

Industry indicated that often these barriers to trade would not be visible, as industry tended to modify its labelling from one country to another, instead of going to the courts.

In the following table we provide an overview of the barriers to trade that have been reported by stakeholders.

2. Comparative Table: Barriers to Trade

no particular problem problem important problem

Country	Nutritional Claims	Health Claims	Ethical Claims	Comments
EU	×		×	CIAA considered the fact that one could not use the same health claim across Europe a clear barrier to trade.
Austria	×		×	Industry indicated that barriers to trade existed, in particular, between Austria and Germany (same language used on labels) because of the stricter Austrian legislation. Also, the Austrian pre-clearance system was considered a barrier to trade.
Belgium	×		×	Industry indicated trade barriers, in particular between Belgium and The Netherlands (same language used on labels). Furthermore, the Belgium notification and authorisation system is considered a barrier to trade.
Denmark	×	×	×	
Finland	×	×	×	
France	×		×	Industry considers the current pre-clearance system for health claims a barrier to trade.
Germany	×		×	Authorities indicated that sometimes problems arise with food supplements, which are often classified as medicinal products in Germany because of the claims made.
Greece	×	×	×	
Ireland	×	×	×	There are fears that the UK Joint Health Claims Initiative may lead to barriers to trade.
Italy	×		×	Industry indicated that imports from other Member States may sometimes cause problems, because of the strict application of the ban on health claims in Italy.
Luxembourg	×	×	×	Due to Luxembourg's proximity to the markets of its neighbouring countries it is basically forced to accept their products on its market.
Netherlands	×	×	×	
Portugal	×		×	Industry considers itself disadvantaged, as the authorities have, on the one hand, a restrictive practice vis-à-vis health claims, but allow, on the other, the import of far-reaching health claims from other Member States.
Spain	×	×	×	
Sweden	×	×	×	The Swedish Board of Trade fears that the increasingly used voluntary labelling systems (also in the area of ethical claims) may potentially cause barriers to trade.
UK	×		×	There seem to exist barriers to trade with regard to borderline cases between food and medicinal products. Potentially, claims allowed under the Joint Health Claims Initiative may not be allowed elsewhere in Europe and thus create barriers to trade.
United States	×	×	×	The saturation of the US market, specifically for dietary supplements may lead to an increase of the export of such products to Europe, potentially creating trade problems, as a result of the far-reaching claims allowed in the US.
Canada	×	×	×	Barriers to trade seem, at the moment, more likely to appear between Canada and the US, than between Canada and Europe.

3. Recommendations

Barriers to trade seem to be generated mainly by the different interpretation that Member State authorities give to the ban spelled out in article 2 of Directive 79/112, i.e. to the ban on claims as to the prevention, treatment and curing of disease, as well as to the development of voluntary agreements on health claims.

It seems that an amendment to the Misleading Advertising Directive will not resolve these barriers to trade. In our view, these problems could essentially be resolved though an amendment of the Labelling Directive 79/112. It would be necessary to clarify the scope of its article 2 and to put it in line with developments at Codex Alimentarius, as well as national voluntary codes on health claims.

D. SUBSTANTIATION NEEDED FOR CLAIMS

1. Comment

With regard to the criteria for substantiating claims, one has to distinguish between nutritional claims, health claims and ethical claims, and as to whether these substantiation criteria are listed in voluntary instruments or in laws.

Nutritional Claims: national legislation most often only applies the criteria set out in the Directive 90/496 on Nutritional Labelling, i.e. whenever a nutritional claim is made nutritional labelling becomes compulsory. In some countries, additional guidelines (e.g. Finland) and/or legal requirements exist as to the composition of the product, that have to be respected in order to be able to make certain nutritional claims (e.g. UK, Germany).

Health Claims: in many cases criteria for substantiating these claims do not exist by law, as health claims are simply not allowed, or criteria for substantiating these claims only apply for some exceptions which are allowed for foodstuffs for particular nutritional uses (PARNUTS). In these cases, a manufacturer has, most often, to submit the label and information on the composition of the product.

In some Member States, and in particular in those where a pre-clearance for health claims exists (Austria, France), criteria have been set out for substantiating claims. Here again, in general the label and information on the composition of the product has to be submitted. Furthermore, some countries also require scientific data to be submitted (e.g. France).

Voluntary instruments on health claims: All of them require, in general, the submission of scientific evidence. The voluntary instruments very often define in more detail the criteria that the scientific evidence must fulfill. Most interesting in this respect is the CIAA draft code on health claims, which lists a large number of criteria that must be fulfilled for substantiating a claim.

Ethical claims: there exists, so far, no legislation on ethical claims. The only two countries working on legislation are Belgium and Italy. In Belgium, once the basic law on the "promotion of socially responsible production" has been adopted, the criteria for obtaining the relevant label still need to be determined in the form of a Royal Decree.

Voluntary agreements on ethical claims: in general, where such voluntary agreements exist, these contain criteria for substantiation. Fair trade labelling schemes apply, generally, the criteria set out by the Fair Trade Labelling Organisation (FLO). These criteria are normally: purchase only from accepted sources; payment of a premium in addition to the market price; respect of minimum labour standards; etc.

The following table provides an overview as to whether provisions on the substantiation of nutritional, health and ethical claims are set out by law or in voluntary agreements.

2. Comparative Table: Substantiation of Claims

Country	Nutritional claims regulated by law	Nutritional claims regulated by voluntary instruments	Health claims regulated by law	Health claims regulated by voluntary instruments	Ethical claims regulated by law	Ethical claims regulated by voluntary instruments
EU		x	(for PARNUTS only)		x	
Austria		x		x	x	x
Belgium		x	(for PARNUTS and fortified foods only)		x (still to be determined by Royal Decree)	
Denmark		x	x (h.c. not allowed)	x	x	
Finland		(Government guidelines)		x	x	
France		x		x	x	
Germany		x	(for PARNUTS only)	x	x	
Greece		x	x	x	x	x
Ireland		x	x (h.c. not allowed)	x	x	
Italy		x	x (h.c. not allowed)	x	x	x
Luxembourg		x	x (h.c. not allowed)	x	x	
Netherlands		x	x		x	
Portugal		x	x (h.c. not allowed)	x	x	x
Spain		x			x	x
Sweden		x	x		x	
UK		(FAC guidelines)	x		x	
Total	**15/15**	**2/15**	**7/15**	**5/15**	**0/15**	**10/15**
USA		x		x	x	x
Canada		x	x (only structure/function claims allowed)	x	x	x

3. Recommendations

Nutritional Claims: substantiation of nutritional claims is mainly based on the respect of certain compositional criteria. It may be advisable to introduce into the Misleading Advertising Directive a general provision that any claim made has to be substantiated through verified facts and data (see also below recommendation regarding ethical claims). Furthermore, it would seem useful to introduce a specific obligation that nutritional claims need to be based on sound scientific evidence (for further details see below recommendations on health claims).

Health Claims: in view of the fact that an increased use of health claims can be expected over the coming years, and in view of the fact that criteria on the substantiation of health claims are mostly listed in voluntary instruments, it may prove useful to introduce a provision into the Misleading Advertising Directive that health claims must be based on sound scientific evidence. All parties seem to agree that health claims should be based on sound scientific evidence. Further details as to the specific criteria that should apply to the scientific evidence, should be introduced via vertical legislation, i.e. Directive 79/112.

This would, however, require a definition of 'health claims' to be introduced into the Misleading Advertising Directive. While it seems useful to introduce a definition of 'claims' into the Directive (see chapter on Definitions, Legislation, Policy Developments and Stakeholders' Positions), it can be questioned as to how far a definition of 'health claims' should not be left to vertical legislation, i.e. Directive 79/112.

The problem could be overcome, if the provision was drafted in such a way that it is clear that only those claims must be based on sound scientific evidence, which are based on the composition and/or quality of the product. This would encompass nutritional and health claims, as well as green claims, whilst it would exclude certain ethical claims from the obligation to be based on sound scientific evidence.

It is clear that certain ethical claims, such as 'produced without child labour' cannot be based on scientific evidence, as they are not based on the composition of the product or quality of the product. Whilst some ethical claims, and notably the fair trade claims, for which some fair trade labelling schemes require also the respect of certain environmental requirements, would, with this approach, fall under the obligation of sound scientific evidence.

This solution would also automatically eliminate any disputes as to whether specific claims fall under the chosen definition of health claims and whether, for these specific claims, scientific evidence was, therefore, needed.

Ethical claims: it appears that there exist a number of criteria used in fair trade labelling schemes. But no criteria are fixed in legislation. In view of the fact that a more widespread use of ethical claims can be expected over the coming years, it may be worth considering to the introduction into the Misleading Advertising Directive of a general provision that any claim made has to be substantiated through verifiabled facts and data.

More specific criteria with regard to the substantiation of ethical claims should be addressed via (new) vertical legislation. So far, due to the limited use of ethical claims, specific vertical legislation on ethical claims, does not yet seem to be a necessity.

E. EXISTENCE OF PRE-CLEARANCE AND POST-CLEARANCE

1. Comment

Pre-Clearance: While in most Member States no pre-clearance rules apply by law, there exist in a large number of informal pre-clearance rules, whereby companies can ask their local enforcement authorities to verify to what extent the claims that the producer wants to use may be considered lawful.

In some Member States more formalised pre-clearance rules exist, but which are equally not set out by law. This is notably the case in countries which rely on self-regulatory instruments such as the UK, Ireland and The Netherlands.

Most interesting in this respect is the UK's Joint Health Claims Initiative. The code introduces the possibility for companies to ask for pre-market advice for innovative health claims. Acting upon pre-market advice suggests the exercise of due diligence. The courts may take this into account in the event of any legal challenge to the health claim under the Food Safety Act.

Systems of pre-clearance have been set up in France and Austria, whereby authorisations from the relevant administrations are needed in order to be able to make health claims. These systems do not apply to ethical claims. In the USA, a pre-clearance system that is administered by the FDA applies for nutritional and health claims.

Belgium applies a somewhat different system, which is not dealing specifically with the claims that are being made, but which allows also for claims to be checked as part of the authorisation system. Thus, an authorisation is needed for foodstuffs for particular nutritional uses. In order to obtain an authorisation, the proposed label and information on the composition of the product has to be sent to the Food Inspectorate of the Ministry of Health. Equally, for nutrients and foodstuffs to which nutrients have been added, an a priori notification procedure applies. Also in this case the labelling has, inter alia, to be sent to the Food Inspectorate.

It is interesting to note that, in The Netherlands and Germany, pre-clearance is considered censorship and is, therefore, not applied.

Post-Clearance: As to post-clearance systems, these are in general undertaken by the relevant health or food inspection services. In some countries the authorities dealing with trading standards are also responsible for post-clearance (e.g. UK, Portugal).

In nearly all Member States, for foodstuffs for particular nutritional uses as defined under EU Directive 89/398, the system of notification is used as a means of pre-clearance of health claims. It is interesting to note that, in Italy, fortified foods and diet integrators also fall under the notification procedure for foodstuffs for particular nutritional uses.

In a number of Member States, formalised out-of-court post-clearance systems apply, mostly in the framework of voluntary codes on advertising (e.g. Germany, Greece, Italy, Ireland, etc.). It seems that competitors quite often make use of these systems. In the following tables, we provide an overview of the pre-clearance and post-clearance systems which apply by law. This is subdivided into pre-clearance applying by law to nutritional and health claims on the one hand and to ethical claims on the other hand. The second table gives an overview of voluntary codes on health claims which foresee a pre-clearance system.

2.a) Comparative Table: Pre-Clearance/ Post-Clearance - BY LAW

Country	Pre-Clearance (by law) Nutritional + Health Claims	Pre-Clearance (by law) Ethical Claims	Post-Clearance (by law) All types of claims	Comments
EU	x	x		
Austria		x		Austria applies a system of pre-clearance for nutritional and health claims.
Belgium		(still to be defined by Royal Decree)		Belgium applies a system of authorisation for foodstuffs for particular nutritional uses for which no EU rules are in place and a system of prior notification for nutrients and foodstuffs to which nutrients have been added if no EU rules are in place. In both cases labels are checked.
Denmark	x	x		
Finland	x	x		
France		x		A 'visa' is required for advertising of products presented as beneficial for health.
Germany	x	x		Pre-clearance is considered censorship and is, therefore, not applied.
Greece	x	x		
Ireland	x	x		
Italy	x	x		The Italian draft law on the certification of products produced without child labour does not foresee an a priori control.
Luxembourg	x	x		
Netherlands	x	x		Pre-clearance is considered censorship and is, therefore, not applied.
Portugal	x	x		
Spain	x	x		
Sweden	x	x		
UK	x	x		
Total	**3/15**	**1/15**	**15/15**	
USA		x		For nutritional and health claims a priori approval system applies. Nevertheless, in 1997, an alternative approach based on authoritative statements of federal scientific bodies via a pre-notification system was introduced.
Canada	x	x		

2.b) Comparative Table: Pre-Clearance/Post-Clearance - IN VOLUNTARY CODES ON HEALTH CLAIMS

Country	Existence of Pre-Clearance	Comments
EU	x	CIAA Code has different objective: deals mainly with substantiation of health claims.
Austria	Not applicable	
Belgium	x	The draft voluntary code does not foresee pre-clearance**.**
Denmark	Not applicable	
Finland	Not applicable	
France	Not applicable	
Germany	Not applicable	
Greece	Not applicable	Possible differences in how strictly legislation is implemented depending on the means of communication used (absence of a relevant body for the control of claims).
Ireland	Not applicable	
Italy	Not applicable	
Luxembourg	Not applicable	
Netherlands		The Dutch code on health claims requires evidence for health claims on foodstuffs to be scientifically founded and reported. It can, therefore, be considered a system of pre-clearance.
Portugal	Not applicable	
Spain	x	The Spanish code on health claims foresees only a system of post-clearance.
Sweden	x	It is being discussed to extend the Swedish code on health claims to product-specific physiological claims, for which a pre-clearance would apply.
UK		The Joint Health Claims Initiative encourages manufacturers to seek pre-clearance of health claims. Acting upon pre-market advice suggests the exercise of due diligence. The courts may take this into account in the event of any legal challenge to the health claim under the Food Safety Act.
Total	**2/6**	
United States	Not applicable	
Canada	Not applicable	

3. Recommendations

Consumer associations are widely in favour of pre-clearance with regard to health claims in order to ensure that only truthful and non-misleading claims are being used. For the following four reasons industry, by contrast, has indicated that it was, in general, opposed to pre-clearance procedures, as:

- these would delay the placing on the market of a product, which is crucial for the food industry since it is a fast moving market;
- it makes it impossible to copyright final food products and/or the claim made;
- industry was worried that confidentiality was not ensured during an a priori approval procedure; and
- it was unproportional to introduce a strict system of pre-clearance.

In the light of diverging these positions, the following options could be considered:

a) Pre-Clearance for all Claims

Introduction of a pre-clearance system that would allow for fast pre-clearance, i.e. within 1 to 2 months. The advantage of a pre-clearance system for all claims is that it would ensure that, in most cases, only truthful and non-misleading claims are made.

The disadvantages of such a pre-clearance system is that it is, from an administrative point of view, very burdensome (and raises the question of whether an EU level pre-clearance authority would need to be established, in order to avoid barriers to trade due to differing pre-clearance advice in the Member States). Furthermore, even under a pre-clearance system, it cannot be excluded that some economic operators may make misleading claims. Finally, even pre-clearance from a government authority, does not give 100% insurance to an economic operator that a court may not find the claim unlawful.

b) Pre-Clearance only for Innovative Claims

A second option is to establish an EU list of generic claims for which no pre-clearance is needed, whilst for all other claims (new/innovative) pre-clearance is needed. This is the approach chosen in the USA. Canada is currently considering following this approach. The establishment of such a generic list could, in our view, only be done via Directive 79/112 on the Labelling of Foodstuffs. It also raises the question of how a list of generic ethical claims could be established and in how far this could be added to the Misleading Advertising Directive.

c) Notification Procedure

A third option would be to introduce a notification procedure, such as the one under Directive 89/398 on Foodstuffs for Particular Nutritional Uses, whereby an operator has to notify to the authorities the placing on the market of a foodstuff for particular nutritional uses. The producer has to submit the label and, where considered necessary, the manufacturer may also be required to produce scientific evidence and data.

Under such a notification procedure for claims, within a certain period of time, the authorities/or responsible body under a voluntary agreement (as one may consider also allowing notification in

the framework of a voluntary agreement), may be allowed to make comments on the label/claim used or in justified cases, require that the product be withdrawn from the market. The advantage for companies would be that they could put their product on the market immediately without having to await approval as in option a).

The disadvantage of this system seems to be that it may prove difficult for national authorities, from an administrative point of view, to check all labels/claims used. This could partly be overcome if, at the same time, a generic list of claims was established and, in which case, for such generic claims no notification was needed.

d) Due Diligence for Voluntary Pre-Clearance

A fourth option, which has been pursued by the UK Joint Health Claims Initiative, would be to encourage operators to submit, either in the framework of a voluntary agreement or in the framework of an administrative body, the claim that he/she wants to make for pre-clearance.

Companies that follow this pre-clearance procedure could then be considered to have exercised due diligence. The courts may take this into account in the event of any legal challenge to the claims made. The disadvantage of this solution is that, in some Member States (Germany, Italy, Austria), due to the legal systems, courts may be tempted not to take such voluntary pre-clearance into account, in particular where such pre-clearance is done in the framework of a voluntary agreement to which the authorities are not a party.

e) Burden of Proof with the Maker of the Claim

A fifth possible way forward would be to counterbalance the absence of a pre-clearance system by reversing the burden of proof so that the maker of the claim would have to prove the non-misleading character and truthfulness of the claim.

This seems to be a possible way forward, although the dissuasive effect of reversing the burden of proof would need to be examined in more detail. It has, nevertheless, the advantage that it would not impose any new burdens from an administrative point of view (the question of reversal of burden of proof is further discussed in the section 'Burden of Proof').

e) Status Quo

A final option is simply to keep the status quo, i.e. different systems in different Member States. This option does not seem to us to be viable, in view of the fact that more and more health claims are likely to be made over the coming years, thus potentially leading an increasing number of consumer protection problems and barriers to trade.

The most viable solutions are in our view:

- a system of notification; and/or
- the model of assumption of due diligence in case of voluntary pre-clearance; and/ or
- the reversal of the burden of proof.

All three options allow for increased consumer protection, whilst at the same time keeping the administrative burden within reasonable limits. Furthermore, all three options seem to be compatible with voluntary instruments on claims. In particular the model of voluntary pre-clearance, as well as the reversal of the burden of proof concept seem to be systems which could apply to all types of claims.

F. LEGAL PERSONS ENTITLED TO TAKE LEGAL ACTION

1. Comment

In all Member States, the authorities, companies, trade and consumer associations are entitled to take legal action. The only exception is Austria where so far consumer associations are not allowed to take legal action. Nevertheless, the Austrian Law against Unfair Competition is currently being revised, in order to give consumers the right to take legal action.

There are a few countries, which do not allow the individual consumer to take legal action. This is notably the case for Austria and Germany.

In the following table, we provide an overview of those countries where authorities, companies, trade and consumer associations are entitled to take legal action, as well as those countries where the individual consumer can also take legal action.

2. Comparative Table: Legal Persons Entitled to take Legal Action

Country	Authorities/ Companies/ Trade Associations/ Consumer Associations	Individual Consumers	Comments
EU	**X**	**x**	The Misleading Advertising Directive leaves it in principle to the Member States to define those entitled to take legal action. It states, nevertheless, that provisions shall be implemented under which persons or organizations regarded under national law as having a legitimate interest in prohibiting misleading advertising may take legal action.
Austria		**X**	Consumer associations cannot take legal action, but the law is currently being revised.
Belgium			
Denmark			
Finland			
France			
Germany		**X**	
Greece			
Ireland			
Italy			
Luxembourg			
Netherlands			
Portugal			
Spain			
Sweden			
UK			
Total	**15/15**	**13/15**	
USA			
Canada			

3. Recommendations

No problems have been reported with regard to the persons entitled to take legal action, apart from Austria, but here the legislation is currently being modified in this respect.

That individual consumers are not allowed to take legal action with regard to claims in a few Member States, does not seem to have led to any problems in terms of consumer protection.

We consider that no clarifications/changes need to be made to the Misleading Advertising Directive with regard to the legal persons entitled to take legal action.

G. BURDEN OF PROOF

1. Comment

The burden of proof lies in a majority of Member States with the plaintiff. Nevertheless, some Member States have established a system whereby the burden of proof lies with the maker of the claim, in the case that the authorities start an investigation. The latter is reflected in the Misleading Advertising Directive, which under certain circumstances empowers national courts and administrations to require advertisers to furnish evidence as to the accuracy of factual claims in advertising.

It is only the Nordic countries, where the burden of proof lies clearly with the maker of the claim. On several occasions, industry indicated that manufacturers were in practice in any case trying to justify their claims via scientific evidence.

In Germany, it was reported that the burden of proof is creating problems for consumer associations to pursue cases in front of the courts, as they do not have the means of paying an expert who can provide an opinion demonstrating that a certain claim cannot be scientifically proven.

Also, the enforcement authorities, in particular in the UK, have highlighted the fact that taking a manufacturer to court requires enormous resources, which they do not have. Hence, unless they are 100% confident of their case, they will not go to court. Instead, they will enter into negotiations with the maker of the claim to try and resolve the issue out of court. It is difficult to indicate what the extent of out of court settlements is, but we are of the opinion that they are numerous.

The following table provides and overview of those countries where the burden of proof lies with the plaintiff, compared to those countries where the burden of proof lies with the maker of the claim.

2. Comparative Table: Burden of Proof

Country	With the plaintiff	With the maker of the claim	Comments
EU	x	x	The Misleading Advertising Directive empowers under certain circumstances national courts and administrations to require advertisers to furnish evidence as to the accuracy of factual claims in advertising, but it does not as a principle put the burden of proof on the maker of the claim.
Austria			The burden of proof is normally with the plaintiff, but if the authorities start an investigation, the burden of proof is with the maker of the claim.
Belgium		x	
Denmark	x		
Finland	x		
France			The burden of proof is normally with the plaintiff. But where a company has not respected the procedures of the 'visa pp' to obtain an authorisation for the use of health claims, it has to substantiate the claim.
Germany		x	The Federal Court concluded in several judgements that the burden of proof is with the maker of the claim where he/she is using an opinion to justify his/her claim which is controversial amongst experts and without also mentioning the dissenting scientific view.
Greece			Greek legislation is unclear as to with whom lies the burden of proof. Public sector representatives and NGOs indicated that the burden of proof lies in practice with both parties.
Ireland		x	
Italy			The burden of proof is normally with the plaintiff. The Antitrust Authority can, nevertheless under certain circumstances ask the maker of the claims to submit proofs of the material accuracy of the data contained in the advertising.
Luxembourg		x	
Netherlands		x	Under the voluntary Dutch Advertising Code, the Advertising Standard Committee can ask anyone using a claim to prove that the claim used is true.
Portugal			The burden of proof is normally with the plaintiff. Nevertheless, under the Advertising Code a company must be able to prove the affirmations on the nature, composition and properties of a good at all times before the competent authorities.
Spain		x	
Sweden	x		
UK		x	
Total	**12/15**	**8/15**	
USA		x	
Canada		x	

3. Recommendations

In those countries where the burden of proof lies with the plaintiff, there seem to exist problems in terms of bringing cases to the courts. Whilst consumer associations are unanimously in favour of a reversal of the burden of proof, industry seems in general to agree that a manufacturer needs to be able to justify nutritional/health claims with scientific evidence. Therefore, we believe that a modification of the rules on burden of proof, as set out in the Misleading Advertising Directive, should take place.

Different options seem to be possible, which have also been discussed by the European Commission in the context of the Green Paper on Liability for Defective Products (COM (1999) 396 final of 28.7.1999, p. 21-23). The following options seem to be possible with regard to claims:

- To impose on the producer the obligation to provide all useful documentation and information so that the plaintiff can avail himself of concrete facts to prove his case.

- To make the producer bear the costs of an expert opinion under certain circumstances, e.g. on condition that the victim reimburses the costs in the event of failure.

- To make the reversal of the burden of proof dependant as to whether the producer has fulfilled certain criteria set out in an amended Directive on Misleading Advertising. The Directive could, for example, set out certain criteria applying to claims, in order to be considered non-misleading (for further details on this point see below section on Voluntary Agreements). If a manufacturer has fulfilled these criteria, the burden of proof would remain with the plaintiff.

- To reverse the burden of proof.

All arguments taken into account and, in particular, if linking the question of burden of proof with the question of pre-clearance (see above under the chapter Pre-Clearance/Post-Clearance), the optimal solution is a reversal of the burden of proof i.e., it would be up to the maker of the claim to prove that the claim is not misleading.

Nevertheless, a reversal of the burden of proof may be considered by some Member States as a profound intervention by the EU into its basic legal principles. In this case, we consider as the second best option to make the reversal of the burden of proof dependant as to whether the producer has fulfilled certain criteria set out in an amended Directive on Misleading Advertising, whilst at the same time requiring the maker of the claim to provide all useful documentation and information so that the plaintiff can avail himself of concrete facts to prove his case.

H. VOLUNTARY AGREEMENTS

1. Comments

The existence of voluntary agreements, shows that where legislation on a particular type of claim exists, the number of voluntary agreements is low. Thus, only in Denmark a voluntary type of agreement on nutritional claims exists, while in Finland and the UK guidelines have been developed by government authorities.

With regard to health claims, numerous voluntary agreements exist or are being planned. Sweden is the country with the oldest code of conduct on health claim, which entered into force in 1990. Due to the fact that more and more stakeholders consider that some sorts of health claims should be allowed, such codes have proliferated across the EU, thus giving a different interpretation to Directive 79/112.

As to ethical claims, being the most recent type of claims made, numerous codes exist. These codes do not specifically deal with claims, but rather set-up labelling initiatives and set out certain criteria that have to be respected, in order to be able to use the logo/symbol of these labelling initiatives. These are mostly fair trade labelling initiatives.

There exist also a number of voluntary agreements on advertising in general in nearly all Member States, which are aimed at providing a sort of voluntary framework to keep advertising within accepted moral and ethical boundaries.

In the following we provide first a table of the voluntary agreements that exist with regard to nutritional claims, health claims and ethical claims. In the second table we provide more information on the voluntary agreements on health claims. In this second table, we have also included the opinion of the French Conseil National de l'Administration, which has set out some criteria as to how health claims should be addressed in the future.

2.a) Comparative Table: Voluntary Agreements

Country	Nutritional Claims	Health Claims	Ethical Claims	Comments
EU			x	The CIAA code on health claims was adopted in September 1999, it deals mainly with the substantiation of claims. Fairtrade Labelling Organizations International (FLO) has established criteria for a number of products.
Austria	X	x	x	
Belgium	X			Code on health claims not yet adopted.
Denmark		x		For nutritional claims, the Nutritional Council, the Regional Food Control Authority of Copenhagen and a so-called "Healthy City-Project" have developed the S-0label to indicate that products are lower in fat and in sugar.
Finland		x		Government guidelines exist on nutritional claims.
France	x	x		No code exists on health claims, but Conseil National de l'Alimentation has adopted an opinion on health claims in 1998, which may serve as a basis for a future EU code.
Germany	x	x		
Greece	x	x	x	
Ireland	x	x		The Irish Business Employers Confederation has initiated the idea of a voluntary code along the lines of the UK Joint Health Claim Initiative.
Italy	x	x	x	
Luxembourg	x	x		
Netherlands	x			Code on health claims initiated by the Dutch Nutrition Center is in force since April 1998. It mainly deals with the substantiation of claims.
Portugal	x	x	x	The Portuguese food industry has had first contacts with the administration on a possible code of conduct on health claims.
Spain	x		x	The Spanish voluntary code on health claims was signed in March 1998.
Sweden	x			The Swedish code on health claims has been in force since 1990.
UK				The Food Advisory Committee has set up guidelines on nutritional claims. The code of the Joint Health Claim Initiative has been finalised, but the code administration body has still to be set up. The Co-operative Wholesale Society has set-up in 1997 its guidelines for nutritional and health claims for labelling of its own products.
Total	**3/15**	**5/15**	**10/15**	
United States	x	x	X	
Canada	x	x	X	The Canadian Food Inspection Agency has published a Guide to Food Labelling and Advertising, aimed at helping inter alia to determining which claims are false, misleading or deceptive.

2.b) Voluntary Agreements on Health Claims

Country	Definitions	Substantiation	Pre-Clearance/Post-Clearance Sanctions	Consumer participation
EU	Defines enhanced function claims and disease risk reduction claims)	CIAA Code provides general and specific principles, including type of evidence required.	**X** Codes main objective is to establish criteria for substantiation No sanctions provided.	None
Belgium	Defines nutrient function claims, health effect claims, healthy eating pattern claims, disease risk reduction claims)	Clear criteria are set. Distinction made between generic claims and new claims in terms of evidence required.	**X** Regarding sanctions, The code only states that it is the responsibility of the one making the claim to ensure its legality	**Active in the elaboration of the Code but hesistant to join as not a priority for them**
Netherlands	Defines health claims that affect human health)	Clear criteria based on scientific evidence, relevance of target population, no clash with dietary guidelines.	Dutch code is aimed at getting evidence for health claims on foodstuffs to be scientifically founded and reported. It can, therefore, be considered a system of pre-clearance. Report on assessment of claim can be made public to third parties.	None
Spain	Gives general definition of health claims)	Criteria set but not binding.	Post-clearance via a follow-up committee X No sanctions	**None**
Sweden	Gives general definition of health claims, which encompasses disease risk reduction)	Criteria set with 8 established diet health connections and 2-step principle of info on product in a balanced diet and info on composition of product and further criteria established for product-specific claims.	X No sanctions	Active and supportive

Country	Definitions	Substantiation	Pre-Clearance/Post-Clearance Sanctions	Consumer Participation
UK	Defines health claim, generic health claim,s innovative health claims and medicinal claims)	The JHCI has set-up detailed criteria; independent expertise to review; needs to be in line with consumer perception, based on legal and nutrition principles. To note that for generic claims, no substantiation required, but for innovative claims it is required.	Joint Health Claims Initiative encourages manufacturers to seek pre-market/clearance of health claims. May make public details of complaint and may disclose details of opinion given on complaint to enforcement and regulatory bodies)	**Active and supportive**
France	CNA opinion contains definitions for risk reduction claims, claims on general contribution to health and functional claims)	CNA calls for precise system; the set-up of an expert external organisation to verify claims; and distinguishes between the scientific substantiation and the communications means	CNA supports pre-clearance of risk reduction claims; supports a posteriori controls. Proposes a requirement to be rigorous in the applications of sanctions on claims, but does not detail them.	**Active and supportive**

3. Recommendations

Three recommendations can be extracted from the voluntary agreements in place. Firstly, there is a need to define claims, as well as health claims. All voluntary agreements on health claims include a definition of health claims. The question of definitions has already been developed further in the above section on Definitions, Legislation, Policy Developments and Stakeholder Positions.

Secondly, there seems to be a need to introduce a provision into the Misleading Advertising Directive requiring Member States to introduce effective and dissuasive sanctions against the use of misleading claims, as only few of the voluntary agreements set out a sanction instrumentarium. This point is developed further below (see section Applicable Penalties).

Thirdly, all voluntary agreements set out certain criteria for substantiation. In particular, the voluntary agreements on health claims list a long number of criteria. Whilst these criteria are evidently focusing very much on food related health claims, some general criteria can be extrapolated. As mentioned in the section on Burden of Proof, an option for reversing the burden of proof, would be to make the reversal of the burden of proof dependant as to whether the producer has fulfilled certain criteria set out in an amended Directive on Misleading Advertising. These criteria could be added to the Misleading Advertising Directive in the form of an annex.

In the following we list a number of criteria, which we have extracted from the voluntary agreements:

Claims must be:

- True and not misleading;
- Clear and understandable;
- Complete (indicate for example for health claims on food the dosage required, the effect over time etc.);
- Precise and not using extrapolations/generalisations (eventually claims using words such as "implies", "suggests" etc. should be considered misleading);
- Objective (e.g. not evoke fears, or if testimonials are used must provide an objective image of the effects that a product claims to have);
- Substantiated, verifiable and documented;
- Supported by scientific evidence if the claim is based on the composition/quality of the product (see also chapter on Substantiation Needed for Claims);

I. APPLICABLE PENALTIES

1. Comment

In all Member States fines and/or imprisonment is foreseen for misleading advertising and/or non-respect of food labelling rules. Nevertheless, in some Member States the penalties/fines seem to be less stringent than in others. The Misleading Advertising Directive only foresees that Member States set up a system which allows for the cessation of the misleading advertising.

2. Recommendations

As mentioned in the previous chapter, one option could be to introduce a provision into the Misleading Advertising Directive, requiring Member States to introduce effective and dissuasive sanctions against the use of misleading claims. This would guarantee the same level of consumer protection in all Member States with regard to the sanctioning of misleading claims.

J. CASE LAW

1. Comment

In a number of Member States, case law on claims could be identified. Most case law relates to health claims. With regard to ethical claims only one case in Germany could be identified.

In general, even in Member States were some case law on health claims exists, this is limited to a few cases. The reason for this seems to be threefold:

1. There seems to be in many Member States a tradition of resolving disputes outside the courts on an informal basis. In particular, countries which rely heavily on self-regulation (e.g. the UK), disputes tend to be resolved outside the legal system.

2. In some countries there seems to be a problem for consumer associations and/or local authorities to bring cases before the courts. This is due to a number of reasons but the most important appears to be cost and the difficulties in securing a judgement as a result of the burden of proof being on the plaintiff to show that the claim is not justified.

3. In countries with a strict legislation and interpretation of health claims by the authorities, producers tend to clarify with the enforcement authorities beforehand in an informal way, in how far there may be objections by the authorities on the use of a certain claim.

Although it is difficult to draw general conclusions from the limited number of case law that exists, it seems that courts tend in general to adopt a rather strict interpretation of health claims. The Member State with the greatest number of case law seems to be Germany. The cases that have been judged by German courts on health claims are for two reasons highly interesting.

Firstly, with regard to the arguments used by German courts against allowing the use of disease related claims. The courts argue that disease related claims in whatever form are not allowed, in order:

- to avoid the danger of self-medication; and
- to avoid that consumers might believe that foodstuffs could have the same effects as medicines.

Secondly, the interpretation of the interdiction to make reference to the prevention, treatment or curing of disease. German courts consider any indirect reference to the prevention or curing of a disease a disease related claim, which is, therefore, forbidden, i.e. a paraphrase of an illness or description of symptoms which can clearly be associated with a certain disease, are considered unlawful.

The European Court of Justice (ECJ) has ruled on a number of cases, which concern the classification of medicines. It is in this context that the Court has also looked at health claims. The rulings indicate that the ECJ gives a broad interpretation to Directive 65/65 on medicinal products, i.e. a product recommended as having

prophylactic or therapeutic properties is a medicinal product, even if it is generally regarded as a foodstuff.

The argumentation used for such a wide interpretation of Directive 65/65 is similar to the one used by German courts, i.e. in order to preserve consumers from products used instead of the proper remedies.

In a more recent case, the ECJ seems to consider that a control system for claims as foreseen under the Misleading Advertising Directive (i.e. that courts and administrations can ask advertisers to furnish evidence as to the accuracy of factual claims, taking into account the legitimate interest of the parties involved) is a viable way of controlling claims.

Although, due to the limited amount of case law, it is difficult to draw general conclusions, it seems that consumer associations or competitors bring cases to the courts and to a lesser degree to the surveillance authorities.

2. Comparative Table: Existence of Case Law

Country	Nutritional Claims	Health Claims	Ethical Claims	Comments
EU	x		x	Most EU case law concerns the definition of a medicinal product, it is in this context that health claims are addressed. The ECJ opts for a wide interpretation of Directive 65/65
Austria	x		x	Austrian courts use a very strict interpretation of disease prevention. A case has also been brought forward to DG XV because of the Austrian pre-clearance system.
Belgium	x	x	x	
Denmark	x	x	x	
Finland	x		x	Finish courts have so far mainly ruled on medical claims used on foodstuffs.
France	x		x	Little case law.
Germany				Large number of case law on health claims. Courts have specifically dealt with the problem of indirect references to diseases in claims. In general, strict interpretation of health claims.
Greece	x		x	Few case law exists, as subject of health claims is in its embryonic stage.
Ireland		x	x	No cases in public law have been reported over past five years. Under the Self-Regulatory Code of the Advertising Standards Authority some very few cases have been dealt with.
Italy			x	No case law could be found in Italian Courts. Nevertheless, the Italian Antitrust Authority has ruled on some few cases, indicating a rather strict interpretation of health claims.
Luxembourg	x	x	x	
Netherlands	x		x	Under the Self-Regulatory Code of the Advertising Code Foundation some cases have been ruled, which indicate a fairly liberal interpretation of health claims.
Portugal	x		x	No case law as such could be found.
Spain	x		x	Only very few case law exists.
Sweden	x		x	Only few case law exists.
UK	x		x	Only very few case law exists, as local enforcement authorities have difficulties in pursuing cases, due to the cost and the difficulties in securing a judgement as a result of the burden of proof being on the plaintiff to show that the claim is not justified.
Total	**3/15**	**10/15**	**1/15**	
USA	x		x	Only few federal court cases exist. Often settlement with the relevant federal agencies. Settlement cases often concern the question of sufficient scientific substantiation.
Canada			x	

3. Recommendations

As mentioned above in a number of Member States disputes are often being resolved in an informal way outside the courts. In order to make such a system work in all Member States, it may be considered necessary to introduce a system as foreseen under Directive 98/27 on Injunctions for the Protection of Consumers' Interests. This Directive foresees that the party that intends to seek an injunction can only start this procedure if it has tried to achieve the cessation of the infringement in consultation with either the defendant or with both the defendant and a qualified entity (i.e. public bodies and organisations whose purpose it is to protect collective interests of consumers).

Access of consumers and even of local enforcement authorities to the courts seems to constitute a problem, because of the difficulties in securing a judgement as a result of the burden of proof being on the plaintiff. It should, therefore, be considered in how far the burden of proof could be reversed, so that it is the maker of the claim who has to provide the proof (see for further details section on Burden of Proof).

K. DIFFERENCES BETWEEN MEANS OF COMMUNICATION

1. Comment

Claims can be made through different means of communication. The most common means are the label of the product and advertising. The countries studied do not differentiate between legislation applicable to labelling and legislation applicable to advertising. In addition to national legislation, self-regulatory rules apply to advertising in certain instances, whereas no such schemes exist for labelling. This, however, does not reflect a difference between the means of communication, since national legislation remains applicable to both labelling and advertising.

Advertising includes a variety of means of communication, such as radio, television, print media and the Internet. Neither the EU countries, nor the United States and Canada make a difference between the standards that apply to the various advertising media.

On many occasions, the internet has been described as a potential source of problems because of the quasi-impossibility to monitor the claims made on the web, as well as the difficulty to control electronic commerce of products bearing prohibited claims. However, policy thinking on this issue is still at a very early stage and no country has taken measures that would apply specifically to the Internet.

2. Comparative Table: Differences between Means of Communication

Country	Difference in legislation applicable to different means of communication (television, radio, Internet, press, labels, etc.)	Comments
EU	No	
Austria	No	
Belgium	No	The only exception is the nutrition labelling legislation, which excludes from its scope audiovisual means of communication.
Denmark	No	
Finland	No	
France	No	
Germany	No	
Greece	No	Possible differences in how strictly legislation is implemented, depending on the means of communication used (absence of a relevant body for the control of claims).
Ireland	No	
Italy	No	
Luxembourg	No	
Netherlands	No	
Portugal	No	
Spain	No	
Sweden	No	
UK	No	The UK relies heavily on self-regulation for the control of claims made in advertising. This leads to the application of different self-regulatory schemes for the various types of media. However, all media are subject to the general provisions of the UK law. In this sense, there is no differentiation between the means of communication.
Total	**15/15**	
United States	No	
Canada	No	

3. Recommendations

All national legislations are based on the principle that a uniform set of rules should apply, whatever the means of communication used. We, therefore, recommend that no difference be made between labelling and advertising, on the one hand, and between the various advertising media, on the other.

In this respect, the scope of the Directive on Misleading Advertising (84/450/EEC) should be clarified, as it is unclear whether its provisions apply to all means of communication and, in particular, claims made on labelling (on-pack claims). We, therefore, recommend that the Directive be amended so that it clearly applies not only to advertising but also to labelling.

This could for example be done by introducing a provision, which would state that the non-respect of labelling legislation shall be considered misleading advertising. This would also be in line with the fact that on a national level, often misleading claims are judged by the courts on the basis of the national rules on misleading advertising/unfair competition.

IV. **COUNTRY SECTIONS**

A. EUROPEAN UNION LEVEL

I. EXECUTIVE ANALYSIS

A. INTRODUCTION

The study was well received by all interested parties at EU level, i.e.., Brussels-based organisations. Those who participated were extremely interested in the study and asked to receive a summary of the study.

B. POSITION OF KEY PLAYERS

1. Nutritional Claims

The definition of a nutrition claim in EU law is very similar to the one used in the Codex Guidelines for Use of Nutrition Claims. The European Consumer Association (BEUC) felt that nutrient content claims should be regulated by clear definitions. The Confederation of the Food and Drink Industries of the EU (CIAA) was in favour of introducing the work that had been undertaken in the Codex Alimentarius on nutritional claims into the Nutrition Labelling Directive via an annex.

2. Health Claims

A number of EU Directives prohibit claiming that a foodstuff may help to prevent, treat or cure a human disease. The same prohibition is contained in the Codex Alimentarius General Guidelines on Claims. Nevertheless, the Codex recently proposed draft recommendations for the use of health claims, which defined enhanced function claims and reduction of disease risk claims. According to this definition, 'risk reduction' is considered not to constitute 'prevention'

The European Parliament stated in its Resolution on the Commission's Green Paper on the General Principles of Food Law of March 1998 that "claims regarding nutritional value and healthy diet and their importance to health and/or in reducing the risk of disease should be allowed".

BEUC considered that it was necessary to work on health claims at EU level, due to the increasing importance of functional foods and due to the fact that several Member States already had voluntary codes in place. BEUC is in favour of strict legislation on health claims.

The association of European Consumer Cooperatives (Eurocoop) also indicated that legislation on health claims was needed at EU level, due to the increasing number of health claims used, particularly on functional foods.

The CIAA considers that there are increasing benefits of highlighting the relationship between nutrition and health in order to reverse the increasing rise in diet-related non-communicable diseases. CIAA considers that the current regulatory framework needs to be adapted, in particular Labelling Directive 79/112, so as to allow disease risk reduction claims.

The European Health Product Manufacturers' Association (EHPM) also considered that there was a need to clarify Directive 79/112. The European Food Law Association indicated that disease risk reduction claims should be allowed via an amendment of Directive 79/112 and Directive 65/65.

The European Retailer Association (Eurocommerce) felt that if new legislation was considered on health claims, it should soften the currently rather strict legislation.

The European Commission Concerted Action on Functional Food Science in Europe (co-ordinated by the International Life Sciences Institute (ILSI)) supports in its consensus document the development of enhanced function claims and reduction of disease-risk claims.

3. Ethical Claims

There exists no EU legislation on ethical claims. The European Commission (DG VIII) is currently finalising a Communication on Fair Trade, which aims to provide an overview of the current activities of the various Commission services in the field of fair trade. No legislative proposals are envisaged at this stage.

Eurocommerce was of the opinion that no legislation on ethical claims was needed since a large number of manufacturers were not using ethical claims. Their reluctance was, indeed, due to the very fact that it was often impossible to ensure the complete veracity of the ethical claims. Furthermore, Eurocommerce felt that since NGOs, trade unions and the press were all very active on ethical issues, the market could regulate false ethical claims itself.

BEUC mentioned that, until now, it has not been asked by its members to look into this issue.

The European Parliament adopted, in January 1999, a Resolution on EU Standards for European Enterprises Operating in Developing Countries. In this Resolution, it calls for the creation of a 'Social Label' together with a Code of Conduct for European businesses that should comprise existing minimum applicable international standards.

C. VOLUNTARY CODES OF PRACTICE

1. Nutritional and Health Claims

There is currently no code of practice at EU level on nutritional claims. In July 1999, the CIAA finalised a code of practice on the use of health claims. The purpose of this code is to help companies to prepare the documentation necessary for the substantiation of health claims, in order to avoid inequalities between Member States. The CIAA aims at getting its code recognised by the European Commission in one form or the other (e.g. via the Standing Committee for Food).

Eurocoop stressed that it considered voluntary codes problematic in terms of control and sanctions. On the contrary, the European Advertising Standards Alliance (EASA)

felt that, in general, industry self-regulation (rather than heavy-handed enforcement by governments) was the best way of regulating claims and other advertising.

2. Ethical Claims

Currently, there exists no EU wide voluntary agreement on ethical claims. While in the textile and retail sector codes have been adopted, which condemn child labour/forced labour and ask member companies to take measures to eradicate child labour, these codes make no reference to labelling/ethical claims.

The Fairtrade Labelling Organizations International (FLO), founded to co-ordinate national fair trade labelling initiatives, has established criteria for a number of commodities, which if fulfilled allow the use of fair trade marks. These fair trade marks do not in general contain any ethical claims as such. Nevertheless, they may be associated by consumers with certain ethical standards. FLO is currently working on the development of a single international fair trade label.

D. VERIFICATION SYSTEMS

With regard to the substantiation of claims, the Nutrition Labelling Directive makes nutrition labelling compulsory whenever a nutritional claim is made. The Directive on Foodstuffs for Particular Nutritional Uses establishes a notification system. The primary purpose of this notification system is not to verify the claim but rather to ensure that the food in question is distinguishable from foodstuffs for normal consumption and is suitable for the claim nutritional purpose. However, several national administrations have indicated that they also verify the claim being made. Under the Directive, companies have to submit a model of the label used and may also be asked to produce scientific work and data.

The European Parliament stated in its Resolution on the Commission's Green Paper on the General Principles of Food Law of March 1998 that claims relating the importance of diet to health and reduction of disease risk should be based on sufficient and recognized scientific findings and be tested and confirmed by an independent body within the EU.

The CIAA code of practice provides for a number of criteria for substantiating health claims. Most importantly, any health claim has to be based on sound scientific evidence and the effect must be quantitatively, statistically and biologically significant. The code lists in further detail these criteria.

As to the burden of proof, the Misleading Advertising Directive addresses the question of burden of proof at the level of courts and administrations. At this level, advertisers have to furnish evidence as to the accuracy of factual claims. Nevertheless, this is conditioned by the fact that courts or administrative authorities shall take into account the legitimate interests of the parties involved. Whilst the CIAA felt that the burden of proof was not something that should be regulated by the EU, it indicated that producers would in any case always have to have all materials available to justify the claim made. Eurocommerce and the European Food Law Association were in favour of putting the burden of proof on the maker of the claim. EHPM considered

that shifting the burden of proof could potentially become very costly for small and medium sized enterprises.

E. MEANS OF COMMUNICATION

In terms of means of communication, the wording used in the Nutrition Labelling Directive, the Foodstuff Labelling Directive, the Directive on Foodstuffs for Particular Nutritional Uses and the Misleading Advertising Directive suggest that they apply to all means of communication.

F. CONSUMER PROTECTION

As far as nutritional claims and consumer protection are concerned, BEUC mentioned that in order to avoid confusion amongst consumers, clear definitions for nutrient content claims should be introduced. Overall, it seems that there are no major consumer protection problems regarding nutritional claims.

With regard to health claims, BEUC felt that a particular problem with health claims was its substantiation. Eurocoop considered it particularly problematic where health claims were used on foods, which from a nutritional point of view, were not highly recommended. (This is sometimes also referred to as food products with a disqualifying composition.) Eurocommerce acknowledged that some claims that were currently used might be misleading. However, this could not be tackled by drafting new legislation, but rather by ensuring that products conformed to the existing legislation.

As to the question of consumer protection and pre-clearance, Eurocoop indicated that it was in favour of pre-clearance. BEUC has not yet finalised its position on this point, but felt at this stage that a pre-clearance procedure may be desirable in order to avoid misleading claims.

The CIAA indicated that it was against pre-clearance systems, as:

- these would delay the placing on the market of a product, which was crucial for the food industry since it was a fast moving market;
- it was not possible to copyright final food product and/or the claim made; and
- industry was worried that confidentiality was not ensured during an a priori approval procedure.

G. BARRIERS TO TRADE

The CIAA indicated that there existed clear barriers to trade since it was not possible to use the same claim in all EU Member States. The CIAA acknowledged that only a few cases had been considered by the European Court of Justice. This was because industry preferred to adapt their label and then to go to court. The CIAA stressed that since the right for information was not the same in all Member States, this was against the Single Market principle. EHPM also felt that there were major impediments to enter different markets in terms of how to get a message across and which claims are actually acceptable.

All interested parties considered that there were no problems in terms of barriers to trade or lack of consumer protection with regard to ethical claims.

H. CASE LAW

There exist only a few cases at the European Court of Justice (ECJ) level that directly deal with health claims. The few that have come to the Court indicate that the ECJ is in favour of a wide interpretation of Directive 65/65 on Medicinal Products, in order to protect the consumer against products used instead of adequate remedies. On the other hand, the ECJ cases seem to indicate that the Court considers a control system for claims as foreseen under the Misleading Advertising Directive (i.e. that courts and administrations can ask advertisers to furnish evidence as to the accuracy of factual claims, taking into account the legitimate interest of the parties involved) as a viable way of controlling claims. The ECJ cases do not provide much information regarding barriers to trade.

I. STAKEHOLDER ANALYSIS

In general, all interested parties seem to agree that there is a need to look into the issue of health claims. Many consider that an amendment to Directive 79/112 was the way forward. Ethical claims are not considered to be a problem so far.

In conclusion, the positions of the main stakeholders are:

1. The European Parliament/Scientific Community

- The recent Resolution of the European Parliament on the Green Paper on Food Law indicates that it is in favour of allowing disease risk reduction claims. These should be based on sufficient and recognized scientific findings and be tested and confirmed by an independent body within the EU.

- The European Commission Concerted Action on Functional Food Science in Europe supports in its consensus document the development of enhanced function claims and reduction of disease-risk claims.

- Both the Concerted Action on Functional Food Science, as well as the Forum on Functional Food of the Council of Europe concluded that claims had to be based on sound scientific evidence.

2. Consumers

- Consumers consider it necessary for the EU to work on the issue of health claims. Consumers are of the opinion that strict conditions should apply for health claims. Eurocoop is clearly in favour of pre-clearance. BEUC has not yet established its position on this point. Consumers want the burden of proof to be with the maker of the claim.

3. Industry

- With regard to health claims, Industry considers it necessary to amend Directive 79/112. Industry is strongly against pre-clearance. With regard to the burden of proof, there is no unanimous view.

- On ethical claims, overall opinion is that no legislation is needed. The European Parliament argued in its recent Resolution on EU Standards for European Enterprises Operating in Developing Countries for the creation of a 'Social Label' together with a Code of Conduct for European businesses. This should comprise existing minimum applicable international standards.

* * *

II. POLICY

A. DEFINITION OF CLAIMS

1. Nutritional Claims

Directive 90/496 on the Nutrition Labelling for Foodstuffs (see Annex 1) defines a nutritional claim in article 1, para. 4 (b) as:

"any representation and any advertising messages which states, suggests or implies that a foodstuff has particular nutrition properties due to the energy (calorific value) it
- provides
- provides at a reduced or increased rate or
- does not provide,

and/or due to the nutrients it
- contains
- contains in reduced or increased proportions or
- does not contain.

A reference to qualities or quantities of a nutrient does not constitute a nutrition claim in so far as it is required by legislation".

The Codex Guidelines for Use of Nutrition Claims contain a similar definition to the one used under EU law. It states:

"Nutrition claim means any representation which states, suggests or implies that a food has particular nutritional properties including but not limited to the energy value and to the content of protein, fat and carbohydrates, as well as the content of vitamins and minerals" (article 2.1, CAC/GL 23-1997, see Annex 13).

The Codex Guidelines further distinguish between nutrient content claims (a nutrition claim that describes the level of a nutrient contained in a food), comparative claims (a claim that compares the nutrient levels and/or energy value of two or more foods), nutrient function claims (a nutrition claim that describes the physiological role of the nutrient in growth, development and normal functions of the body). and claims related to dietary guidelines or healthy diets (articles 2.1.1 following, CAC/GL 23/1997).

2. Health Claims

Directive 79/112 on Labelling, Presentation and Advertising of Foodstuffs does not contain a definition of health claims, but establishes a prohibition for certain types of health-related claims. The definition given in article 2 para. 1 (b) is the following (please note we are using here the codified version as published in COM (1999) 113 final, see Annex 3):

"1. The labelling and methods used must not:
[…]
(b) subject to Community provisions applicable to natural mineral waters and foodstuffs for particular nutritional uses, attribute to any foodstuff the property of preventing, treating or curing a human disease, or refer to such properties."

A very similar definition is used in article 6 para. 1 of Directive 89/398 on Foodstuffs intended for Particular Nutritional Uses (see Annex 7):

"The labelling and the labelling methods used, the presentation and advertising of the products referred to in Article 1 must not attribute properties for the prevention, treatment or cure of human disease to such products or imply such properties".

Directive 80/777 on the Exploitation and Marketing of Natural Mineral Waters (see Annex 8) also contains a similar provision in article 9 para. 2 (a):

"All indications attributing to a natural mineral water properties relating to the prevention, treatment or cure of a human illness shall be prohibited".

Directive 65/65 on Proprietary Medicinal Products (Annex 6) uses a similar wording, to define medicinal products. It states (article 1 (2)):

"Medicinal product: Any substance or combination of substances presented for treating or preventing disease in human beings or animals".

The fact that this is used as one of the criteria to define a medicinal product has led to a number of court cases regarding the classification of a product as a foodstuff or as a medicine (see section V.A)).

The Misleading Advertising Directive 84/450 (Annex 4) does not contain any definition of claims. Nevertheless, the question remains whether the definition for advertising as used in the Misleading Advertising Directive also covers 'claims'. The definition used is "the making of a representation in any form in connection with a trade, business, craft or profession in order to promote the supply of goods or services […]" (article 2 (1)). We shall discuss this point further in the section on Recommendations.

The General Guidelines on Claims of the Codex Alimentarius define claims as "any representation which states, suggests or implies that a food has particular characteristics relating to its origin, nutritional properties, nature, production, processing, composition or any other quality" (article 2., CAC/GL 1-1979 (Rev. 1-1991), see Annex 12).

The same Guidelines prohibit claims "as to the suitability of a food for use in the prevention, alleviation, treatment or cure of a disease, disorder or particular physiological condition […]" (article 3.4.).

The latest proposed draft recommendations for the use of health claims of the Codex Alimentarius (Alinorm 99/22A Appendix VII, see Annex 14) establish the following definition for health claims:

"Health claim means any claim establishing a relation between a food or a constituent of that food and health, [whether it is good health or a condition related to health [or disease]].
or

Health claim means any claim which suggests that a food or a constituent of that food has an impact on health."

The Codex draft recommendations further defines two types of health claims:

- Enhanced function claims
- Reduction of disease risk claims

Enhanced function claims are defined in the following way:
"These claims concern specific beneficial effects of the consumption of foods and their constituents on physiological, [or psychological] functions or biological activities but do not include nutrient function claims. Such claims relate to a positive contribution to health or to a condition linked to health or to the improvement of a function or to modifying or preserving health."

Reduction of disease risk claims are defined in the following way:
"Claims for reduction of disease risk related to the consumption of a food or food constituent in the context of the total daily diet that might help reduce the risk of a specific disease or condition".

It is interesting to note that the recommendations clearly state that risk reduction "means significantly altering a major risk factor or factors recognized to be involved in the development of a chronic disease or adverse health-related condition" but does not constitute "prevention".

Enhanced function claims as defined by the Codex recommendations seem to be possible under Labelling Directive 79/112. However, disease risk reduction claims as defined by the Codex recommendations seem to go further than the relevant provisions in Labelling Directive 79/112 (Annex 2).

3. Ethical Claims

EU legislation does not provide for any definition of ethical claims.

B. LEGISLATION IN PLACE

1. Nutritional Claims

Nutritional claims are regulated by Directive 90/496 on Nutrition Labelling for Foodstuffs (Annex 1).

2. Health Claims

Health claims are regulated by Directive 79/112 on Labelling, Presentation and Advertising of Foodstuffs (Annex 2), whereby the relevant article 2 was last amended by Directive 89/395 (Annex 3).

Health claims are also regulated by Directive 89/398 on Foodstuffs intended for Particular Nutritional Uses (Annex 7).

Furthermore, health claims and alcohol advertising are regulated by Directive 89/552 on Television Broadcasting Activities (Annex 9).

In addition, health claims on mineral waters are regulated by Directive 80/777 on the Exploitation and Marketing of Natural Mineral Waters (Annex 8).

Finally, misleading advertising is covered by Directive 84/450 on Misleading Advertising (Annex 4).

3. Ethical Claims

There exists no specific EU legislation on ethical claims.

C. EXISTING PROHIBITIONS, RESTRICTIONS AND EXEMPTIONS

1. Nutritional Claims

a. Prohibitions/ Restrictions

Under the Nutrition Labelling Directive 90/496 (Annex 1), only nutrition claims are permitted, which relate to energy and/or to protein, carbohydrate, fat, fibre, sodium, vitamins and minerals (article 3). Vitamin and mineral claims are limited to those defined in the Annex of that Directive and if these are present in a significant amount. A significant amount is defined as 15% of the RDA (see Annex to Directive in conjunction with article 1, para 4. (a)).

A number of conditions have been set out under the Codex Guidelines for Use of Nutrition Claims (Annex 13) for the use of nutrient content claims, comparative claims, nutrient function claims and claims related to dietary guidelines. In general, only nutrition claims relating to energy, protein, carbohydrate, fat, fibre, sodium and vitamins and minerals for which nutrient reference values have been established are permitted. In particular, for nutrient content claims, with regard to fat, cholesterol, sugars and sodium certain limit values have been established (see article 4.-8., CAC/GL 23-1997).

Furthermore, the General Guidelines on Claims (Annex 12) establish a number of further restrictions, e.g. claims stating that any given food will provide an adequate source of all essential nutrients are forbidden (see in particular article 3., CAC/GL 1-1979 (Rev. 1-1991).

b. Exemptions

The Nutrition Labelling Directive (Annex 1) foresees that within the meaning of its article 3, provisions restricting or prohibiting nutrition claims may be adopted by the Standing Committee for Foodstuffs. Such restrictions or prohibitions have so far not been proposed.

Directive 80/777 on Natural Mineral Waters (see Annex 8) establishes in Annex III a number of criteria for the use of claims such as "low mineral content", "very low

mineral content", "suitable for a low-sodium diet" etc. The criteria used are based on certain threshold limits for these minerals.

Similarly, such nutritional claims may be allowed if they are based on criteria laid down in national provisions. These national provisions have been drawn up on the basis of physico-chemical analysis and, where necessary, pharmacological, physiological and clinical examinations (Article 9 para. 2 (b)).

2. Health Claims

a. Prohibitions/Restrictions

Apart from the prohibition on certain health-related claims (see II.A.2.), the Labelling Directive provides for a prohibition of misleading claims. This is defined in the following way in article 2 para 1:

"1. The labelling and methods used must not:
a) be such as could mislead the purchaser to a material degree, particularly:
(i) as to the characteristics of the foodstuff and, in particular, as to its nature, identity, properties, composition, quantity, durability, origin or provenance, method of manufacture or production,
(ii) by attributing to the foodstuff effects or properties which it does not possess,
(iii) by suggesting that the foodstuff possesses special characteristics when in fact all similar foodstuffs possess such characteristics;"

The Labelling Directive also foresees in article 2 para. 2 that the Council (under co-decision procedure) shall draw up a non-exhaustive list of the misleading claims that must be prohibited or restricted. Such a list has not been drawn up to date.

Directive 76/768 on Cosmetic Products (as amended by Council Directive 88/667 and 93/35, see Annex 31) uses a slightly different wording for misleading claims. Article 6(3) states:

"Member States shall take all measures necessary to ensure that, in the labelling, putting up for sale and advertising of cosmetic products, text, names, trade marks, pictures and figurative or other signs are not used to imply that these products have characteristics which they do not have".

Directive 84/450 on Misleading Advertising (Annex 4) contains a number of criteria for determining misleading advertising. It is interesting to compare these to the ban on misleading claims as set out under the Labelling Directive. In article 3(a), the following criteria for determining misleading advertising are listed in the Misleading Advertising Directive:

"the characteristics of goods or services, such as their availability, nature, execution, composition, method and date of manufacture or provision, fitness for purpose, uses, quantity, specification, geographical or commercial origin or the results to be expected from their use, or the results and material features of tests or checks carried out on the goods or services;"

More specific restrictions on the use of certain claims are listed in Directive 89/552 on Television Broadcasting Activities (Annex 9). In article 15, restrictions on television advertising and teleshopping (teleshopping has been added through article 17 of Directive 97/36 amending Directive 89/552, see Annex 10) of alcoholic beverages are laid down:

(b) it shall not link the consumption of alcohol to enhanced physical performance or to driving;
(c) it shall not create the impression that the consumption of alcohol contributes towards social or sexual success;
(d) it shall not claim that alcohol has therapeutic qualities or that it is a stimulant, a sedative or a means of resolving personal conflict
(e) it shall not encourage immoderate consumption of alcohol or present abstinence or moderation in a negative light;"

The Codex General Guidelines on Claims (Annex 12) are based on the principle that no "food should be described or presented in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect" (article 1.2., CAC/GL 1-1979 (Rev. 1-1991)). Furthermore, the same guidelines prohibit the use of claims, which cannot be substantiated, as well as potentially misleading claims. The guidelines give examples of meaningless claims. These include incomplete comparatives and superlatives and claims as to good hygienic practice, such as wholesome, healthful, sound (article 3.3. and 4., CAC/GL 1-1979 (Rev. 1-1991)).

b. Exemptions

The Directive on Foodstuffs for Particular Nutritional Uses (Annex 7) provides in article 6 for an exception to the general ban on claims making reference to the prevention, treatment or cure of human diseases. It is stated that the Standing Committee for Foodstuffs may adopt derogations in "exceptional and clearly defined cases". Such derogations have so far not been adopted by the Standing Committee for Foodstuffs.

The Directive on Natural Mineral Waters (Annex 8) provides for a number of exemptions to the general interdiction of claims making reference to the prevention, treatment or cure of human diseases.

Member States may thus authorize: "the indications 'stimulates digestion', 'may facilitate the hepato-biliary functions' or similar indications." (Article 9 para. 2 (c))

Under the same Directive, Member States may also authorize the inclusion of other indications, provided that these do a) not conflict with the principle that attributions to the prevention, treatment or cure of a human illness is forbidden and b) are compatible with the criteria listed in Annex III of the Directive or national criteria.

The Codex Alimentarius General Guidelines on Claims (Annex 12) provide for an exception with regard to claims on the prevention and treatment or cure of diseases in two cases. Firstly, the Codex Committee on Foods for Special Dietary Uses may approve guidelines for claims made on foodstuffs for special dietary uses. Secondly,

an exception is provided for where the Codex standards on claims are not yet applied under the laws of a country (article 3.4 CAC/GL 1-1979 (Rev. 1-1991).

3. Ethical Claims

There exists no specific EU legislation on ethical claims. Nevertheless, the Misleading Advertising Directive 84/450 can be seen as providing for certain restrictions and prohibitions, as it defines misleading advertising as "any advertising which in any way, including its presentation, deceives or is likely to deceive the persons to whom it is addressed or whom it reaches and which, by reason of its deceptive nature, is likely to affect their economic behaviour or which, for those reasons, injures or is likely to injure a competitor" (article 2 (2)).

D. POLICY THINKING AND STAKEHOLDERS' POSITIONS

1. Nutritional Claims

The Confederation of the Food and Drink Industries of the EU (CIAA) was in favour of introducing the Codex work on nutritional claims into the EU via an annex to the Nutrition Labelling Directive.

The European Consumer Association (BEUC) felt that nutrient content claims should be regulated by clear definitions.

2. Health Claims

BEUC felt that it was necessary to work on health claims at EU level, due to the increasing importance of functional foods and due to the fact that several Member States had already voluntary codes in place.

BEUC is currently working on finalising its position on health claims. It hoped to have done this during 1999. The following information does, therefore, not represent the final BEUC position, which is still in the process of being elaborated.

BEUC indicated that it was in favour of strict legislation on health claims. BEUC also mentioned that it was probably not possible to establish a positive/negative list of claims. Instead criteria would be needed, in order to ensure that only true and non-misleading claims were being made.

In its submission to the Green Paper on Food, BEUC supported the following policy: "Health claims should not convey the unjustified message to consumers that an appropriate diet could be replaced by eating particular products. If health claims are permitted at all, they should preferably be generic claims which reflect significant agreement among qualified experts, supported by the totality of publicly available evidence and which contribute to inform consumers about the relationship between diet and health." (see Annex 20).

The association of European Consumer Cooperatives (Eurocoop) indicated that due to the increasing number of health claims used, particularly on functional foods, legislation on health claims was needed at EU level. While Eurocoop is rather critical

about health claims, it acknowledges that it is not possible to ban them. Legislation should establish criteria under which conditions a claim could be allowed. It felt that for some claims a positive list could be established, where the link between a certain ingredient/nutrient and a health condition has been scientifically proven. They also raised the particular problem that health claims are used on foods, which were, from a nutritional point of view, not highly recommended (e.g. vitamin C in foodstuffs with a high fat content).

The European Advertising Standards Alliance (EASA) felt that in general industry self-regulation, rather than heavy-handed enforcement by governments, was the best approach to regulating claims and other advertising.

The CIAA argues that there are increasing benefits to be made from highlighting the relationship between nutrition and health, in order to reverse the increasing trends in diet-related non-communicable diseases. "CIAA [therefore] believes that it is desirable to optimise the communication on diet-health information to consumers through coordinated and complementary programmes involving food labelling, commercial communications and consumer education" (CIAA Position Paper on Claims on Nutrition and Health, February 1999).

Furthermore, the CIAA stresses that improving health-promoting properties of foodstuffs is expensive. "Manufacturers will be reluctant to continue to invest in this type of research if claims concerning these health benefits are not allowed" (CIAA Position Paper on Claims on Nutrition and Health, February 1999, see Annex 23).

CIAA considers that the current regulatory framework needs to be adapted, in particular Labelling Directive 79/112, so as to allow disease risk reduction claims. Claims that a food can treat or cure a disease should continue to be forbidden.

The CIAA indicated that since it was not possible to use the same claim in all EU Member States, there clearly existed some barriers to trade. CIAA gave the example of a functional yoghurt, for which a different claim had to be used in nearly every Member State (e.g. in Germany "for your well-being", in Spain "protects the body" etc.). The CIAA acknowledged that only a few cases had been looked at by the European Court of Justice. Industry prefers to adapt its label instead of going to court. The CIAA stressed that it was against the Single Market principle that the right for information was not the same in all Member States.

The European Retailer Association (Eurocommerce) felt that no further legislation was needed at EU level on health claims. If new legislation was considered, it should be a way to soften the currently rather strict legislation, e.g. enhanced function claims should be clearly allowed. They added that the European Commission should ensure that sufficient food controls were done at Member State level. Eurocommerce also indicated that as retailers, they were not experiencing any particular barriers to trade.

The European Health Product Manufacturers' Association (EHPM), which is an association of federations dealing with health products such as food supplements, herbals and health foods, considered that there was a need to clarify Directive 79/112, as they felt that the current legal framework was not appropriate, given the wording of article 2 of that Directive and the need for broader interpretation. EHPM mentioned

the same example of a functional yoghurt. EHPM felt that this case demonstrated that there are major impediments to enter different markets in terms of how to get a message across and which claims are actually acceptable.

The European Food Law Association, an international scientific association that mainly aims to study food law and to contribute to its international harmonisation, is currently finalising a position paper on health claims. EFLA is of the opinion that disease risk reduction claims should be allowed via an amendment of Directive 79/112 and Directive 65/65.

The European Commission Concerted Action on Functional Food Science in Europe (FUFUOSE), which is co-ordinated by the International Life Sciences Institute (ILSI), supports in its consensus document on "Scientific Concepts of Functional Foods in Europe" the development of two types of health claims: enhanced function claims and reduction of disease-risk claims (see Annex 14).

The Concerted Action definitions are very similar to the ones that have been introduced in the latest Codex draft recommendations on health claims. The definitions are the following:

Enhanced function claims: "These claims concern specific beneficial effects of nutrients and non-nutrients on physiological, psychological functions or biological activities *beyond their established role* in growth, development and other normal functions of the body".

Reduction of disease-risk claims: "Claims for reduction of disease risk relate to the consumption of a food or food component that might help reduce the risk of a specific disease or condition because of specific nutrients or non-nutrients contained within it." (Scientific Concepts of Functional Foods in Europe: Consensus Document, in: British Journal of Nutrition, Volume 81 Supplement Number 1 1999, page S24, Annex 15)

The European Parliament stated in its Resolution on the Commission's Green Paper on the General Principles of Food Law of March 1998 that "claims regarding nutritional value and healthy diet and their importance to health and/or in reducing the risk of disease should be allowed" (point 66, see Annex 16).

3. Ethical Claims

Eurocommerce felt that no legislation on ethical claims was needed. This was because many manufacturers were abstaining from using ethical claims since it was often impossible to ensure the 100% veracity of an ethical statement such as 'no child labour'. This was also the case for companies that had very strict control mechanisms in place with regard to child labour.

Furthermore, Eurocommerce indicated that legislation on ethical claims would not be useful, as it was virtually impossible to enforce and control. Finally, NGOs, trade unions and the press were all very active on ethical issues. The market could, therefore, regulate false ethical claims itself.

BEUC indicated that it had no position on ethical claims, as it had never been asked by its members to look into the issue.

The European Parliament adopted on 15 January 1999 a Resolution on EU Standards for European Enterprises Operating in Developing Countries (Annex 17). In this Resolution the European Parliament reaffirms its support for the creation of a 'Social Label' together with a Code of Conduct for European businesses that should comprise existing minimum applicable international standards. Parliament also calls upon the Commission to study the possibility of setting up a European Monitoring Platform. The Resolution does not contain any further details regarding social labels.

The European Commission (DG VIII) is currently finalising a Communication on Fair Trade, which is due to be adopted by the college of Commissioners before the end of the year. The Communication aims at giving an overview of the current activities of the various Commission services in the field of fair trade. The Communication does at this stage not propose any legislation in this area.

III. VOLUNTARY INSTRUMENTS AND OTHER PRACTICES

A. VOLUNTARY INSTRUMENTS IN PLACE/PLANNED

1. Nutritional

Currently, there exist no voluntary instruments on nutritional claims at the EU level. CEEREAL, the European Breakfast Cereal Association has, nevertheless, developed some guidelines for quantitative nutrition claims for breakfast cereals.

2. Health Claims

The Confederation of the Food and Drink Industries of the EU (CIAA) finalised in July 1999 a code of practice on the use of health claims (Annex 21). The CIAA indicates that the purpose of the code is to help companies to prepare the documentation necessary for the substantiation of health claims, in order to avoid inequalities between Member States.

Eurocoop indicated with regard to voluntary codes of conduct that whilst these may work in some Member States, they would not in other Member States, such as Italy. Voluntary codes were problematic, as it was difficult to ensure control and sanctions. Eurocoop, therefore, favoured legislation.

BEUC stressed that it was still working on its position on health claims. At this stage it could only indicate that if there were to be a code of conduct at EU level, it was crucial that such a code was also enforceable.

The CIAA saw its own work on a European Code of Conduct on health claims as an intermediate step prior to changes to Directive 79/112. The CIAA acknowledged that in some Member States, such as Italy, a code may not work.

3. Ethical Claims

Currently, there are no EU wide voluntary agreements on ethical claims.

In the textile and retail sector, codes have been adopted which condemn child labour/ forced labour and ask member companies to take measures to eradicate child labour. However, these codes make no reference to labelling/ethical claims (see notably Charter by European Social Partners in the Footwear Sector on Child Labour, March 1995 (updated 1997); Charter by the Social Partners in the European Textile and Clothing Sector, September 1997; Eurocommerce and Euro-Fiet Joint Statement on Combating Child Labour, March 1996, see Annex 30).

With regard to fair trade products, in 1997, Fairtrade Labelling Organizations International (FLO) was founded. This aims to co-ordinate national fair trade labelling initiatives. FLO members include the Max Havelaar Foundations, as well as the TransFair fair trade labelling organisation and the European Fair Trade Association. A central responsibility for FLO is to collect data and ensure the audit of all fair trade labelled products. FLO is currently working on the development of a single international fair trade label.

To date, FLO has established criteria for a number of products (coffee, cocoa, bananas, orange juice, sugar, tea and honey), which if fulfilled allow the use of fair trade marks. These fair trade marks do not, in general, contain any ethical claims as such. Nevertheless, they may be associated by consumers with certain ethical standards.

The FLO criteria are generally divided into two parts: criteria applying for the importer and criteria applying for the producer. The main criteria for the importer are that he has to buy the product only from accepted sources which are declared in an International Producer Register (there are registers for each product) administered by the FLO. Furthermore, he has to pay a premium in addition to the market price. The premium will be re-channeled to the producers. Producers, in order to be inscribed in an International Producer Register have to respect minimum labour standards, a ban on child labour, equal treatment etc. Furthermore, several of the International Producer Registers also contain certain environmental minimum standards that have to be fulfilled (see attached the FLO Criteria for coffee, cocoa, bananas, orange juice, sugar, tea and honey, Annex 29).

The European Fair Trade Association (EFTA) is an association of twelve importers in nine European countries. EFTA sees as its core business to make fair trade importing more efficient and effective. EFTA provides services to its members, such as information exchange on products and producers, encouraging bilateral cooperation and the development of a common database. EFTA has developed Fair Trade Guidelines (see Annex 28). These guidelines are divided into Register Guidelines (applying to producers) and Trading Guidelines (applying to EFTA members).

These guidelines state that EFTA will work with companies of marginalized producers, employees, and Southern organisations, which seek to support sustainable development through providing regular income, protect human rights, protect the

environment etc. The guidelines state with regard to EFTA members that they shall provide continuity of relationships through the provision of regular orders, fair prices which provide a reasonable return to the producer, pre-financing, and assistance in product development, etc. The guidelines do not address the issue of ethical claims.

B. DEFINITIONS USED IN THE VOLUNTARY INSTRUMENTS

1. Nutritional Claims

Not applicable.

2. Health Claims

The CIAA code of practice (Annex 21) distinguishes between two types of health claims. Firstly, function claims, which are defined in the following way (IV. 2.1.):

"These claims concern specific beneficial effects of nutrients and non-nutrients on a physiological, psychological functions or biological activities beyond their established role in growth, development and other normal functions of the body."

Secondly, reduction of diseases risk claims, which are defined as (IV. 2.2):

"Claims for reduction of disease risk related to the consumption of a food or food component that might help reduce the risk of a specific disease or condition because of specific nutrients or non-nutrients contained within it".

3. Ethical Claims

The FLO criteria lists (Annex 29) and EFTA guidelines (Annex 28) do not make any reference to ethical claims. The same holds for the child labour codes mentioned above.

C. EXISTING PROHIBITIONS, RESTRICTIONS AND EXEMPTIONS

1. Nutritional Claims

Not applicable.

2. Health Claims

The CIAA code of practice makes it clear that it does not apply to pharmaceutical products and that it only applies to the two types of health claims described above.

3. Ethical Claims

No restrictions, prohibitions or exemptions are mentioned in the FLO criteria list and EFTA guidelines with regard to ethical claims. The same applies to the child labour codes mentioned above.

D. VOLUNTARY INSTRUMENTS ACCEPTED/RECOGNISED BY THE AUTHORITIES

1. Nutritional Claims

Not applicable.

2. Health Claims

The CIAA aims to have its Code of Conduct in some form recognised by the European Commission (e.g. via the Standing Committee for Food).

3. Ethical Claims

The FLO criteria lists and the EFTA guidelines are not recognised by the European institutions.

The charter on child labour of the European footwear sector and the textile and clothing sector (see Annex 30) have been drafted in the framework of the social dialogue, in which the European Commission is a participant.

IV. VERIFICATION SYSTEMS

A. CRITERIA FOR SUBSTANTIATING CLAIMS

1. Nutritional Claims

The Nutrition Labelling Directive (Annex 1) makes nutrition labelling compulsory whenever a nutritional claim is made (article 2 (2)). No further criteria are listed for substantiating a claim.

2. Health Claims

Under EU legislation only the Directive on Foodstuffs for Particular Nutritional Uses (Annex 7) establishes a notification system. The primary purpose of this notification system is not to verify the claim, but rather to ensure that the food in question is distinguishable from foodstuffs for normal consumption and is suitable for the claimed nutritional purpose (see article 1 of the Directive). However, several national administrations indicated that they also verify the claim made (see country section).

Under the Directive, companies are required to send as notification material to the competent national authority "a model of the label used for the product" (article 9 (1)). Where necessary, the manufacturer may also be required to produce scientific work and data establishing the product's compliance with the claimed particular nutritional purpose (article 9 (3)).

The CIAA code of practice (Annex 21) provides for a number of criteria for substantiating health claims. The CIAA code lists a number of general principles:

- "The company responsible for placing a product on the market is responsible that any health claim is based on sound scientific evidence".
- Supporting evidence shall be:
  "Consistent in itself.
  Be able to meet accepted scientific standards of statistical and biological significance.
  Be plausible in terms of the relationship between intervention and results."
- "Any health claim should be supported by appropriate scientific evidence concerning the specific physiological effects which are claimed."
- "Substantiation should demonstrate efficacy with an appropriate amount of intake."
- "Health claims should be justified in the context of the whole diet and must be applicable to the amount of food normally consumed" (point V. of the code).

Furthermore, the code indicates that in order to justify a claim: "The effect must be quantitatively, statistically and biologically significant. The size of the effect measured must be shown to be sufficiently important to justify the claim." (point IV. 8 of code)

The code then lists a number of more specific guidelines for the substantiation of health claims (point VI. 1-5 of code). These are:

- Validation of health claims shall have been carried out alongside all the other checks necessary when examining the suitability of a food product for the purpose for which it is marketed.
- If the composition or manufacturing changes substantially, or new scientific developments occur, additional checks shall be carried out to ensure that the claim is still valid.
- It has to be shown that the specific functional substances are present in the quantity and form needed to justify the claim through shelf life.
- Normal serving size, conditions of use and consumption pattern should be taken into account in the assessment of the relevance of the concerned food.
- The evidence collected must show that consumption of the food can result in the health effects claim. A difference is, nevertheless, being made between 'generic claims' and 'new' claims. For generic claims bibliographic evidence is considered to be normally sufficient. For new claims the scientific evidence required has to be determined on a case by case basis and should include human studies where appropriate.

Regarding this evidence, the code indicates that it could be expected to come from (point VI. 6 of code):

- scientific literature
- in vitro studies
- animal models

- clinical studies
- epidemiological studies
- any other relevant studies

With regard to human studies, a number of criteria are listed in the code (point VI. 7. of the code):

- "They must be carried out in a representative sample of the population.
- The use of internationally accepted and validated methods and of biological markers is recommended when they exist.
- They should demonstrate efficacy with respect to the specific physiological effect(s). An effective level and frequency of consumption should be suggested for a food claiming to have a positive effect on health.
- The effect must be studied over sufficient time to allow adaptation to occur and should consider confounding factors such as health status at the time of the study, use of medication, smoking."

The code also provides for the possibility for companies to have their scientific evidence evaluated by an independent scientific body. The code indicates that the CIAA is in the process of establishing a list of such independent scientific bodies (point VI. 9 of code).

3. Ethical Claims

The FLO criteria lists do not go into further detail with regard to the material that needs to be submitted for substantiating the use of fair trade labels.

B. LEGAL/ADMINISTRATIVE SYSTEMS FOR VERIFYING CLAIMS

1. Pre-Clearance Rules/ Guidelines

No EU system of pre-clearance exists for claims.

The FLO allows importers/ producer organizations to use the fair trade label only once they have fulfilled criteria set out in the criteria lists for the different products covered by FLO.

2. Post-Clearance Rules/ Guidelines

Under EU legislation the Directive on Foodstuffs for Particular Nutritional Uses (Annex 7) establishes a notification system. This notification procedure can be regarded as a post-clearance system (see also IV. A.).

With regard to the FLO, it sends monitoring experts to monitor the producers. Furthermore, the FLO together with its national members monitors the flow of goods.

The Charter on Child Labour of the European Footwear Sector recommends that companies include the Charter in the terms of purchase with their subcontractors and suppliers. No further statement on post-clearance is being made. The Charter of the European Textile and Clothing Sector states that the European Apparel and Textile

Organisation (EURATEX) and the European Trade Union Federation of Textiles, Clothing and Leather (ETUF:TCL) will conduct a yearly evaluation of the Charter's implementation. The results of this evaluation are due to be reported in the framework of the Social Sectoral Dialogue (see Annex 30).

C. LEGAL PERSONS ENTITLED TO TAKE LEGAL ACTION

Under the Misleading Advertising Directive (see Annex 4), it is in principle left to the Member States to define, which persons are entitled to take legal action on misleading advertising. Nevertheless, it is stipulated that legal provisions shall exist "under which persons or organizations regarded under national law as having a legitimate interest in prohibiting misleading advertising" (Article 4) may take legal action or bring such advertising before a competent administrative authority.

D. BURDEN OF PROOF

Article 6 of the Misleading Advertising Directive (as amended by 97/55) addresses the question of burden of proof at the level of courts and administrations. It states that the Member States shall empower courts or administrative authorities "to require the advertiser to furnish evidence as to the accuracy of factual claims in advertising if, taking into account the legitimate interests of the advertiser and any other party to the proceedings, such a requirement appears appropriate on the basis of the circumstances of the particular case and, in the case, of comparative advertising to require the advertiser to furnish such evidence in a short period of time".

The Directive does not address the burden of proof at the level of the complainant.

It is interesting to note that the Codex General Guidelines on Claims (Annex 12) states that "The person marketing the food should be able to justify the claims made" (article 1.3., CAC/GL 1-1979 (Rev. 1-1991)).

E. COMMENTS

The European Parliament stated in its Resolution on the Commission Green Paper on the General Principles of Food Law (see EP Minutes of 10 March 1998, in Annex 16) that food-product health claims should only be authorized "if they are tested and confirmed by an independent body within the European Union and calls on the Commission also to continue in future to ban advertising claims that a particular food is suitable for treating, curing or preventing disease, though claims regarding nutritional value and health diet and their importance to health and/or in reducing the risk of disease should be allowed if they are based on sufficient and recognized scientific findings and if they are tested and confirmed by an independent body within the European Union " (point 66 of Resolution).

While the European Parliament did not make it clear whether it was in favour of pre- or post-clearance, it is clear that Parliament is in favour of clearance via an independent body. Furthermore, in the Parliament's view, claims should be substantiated via sufficient and recognized scientific findings. Again these findings have to be confirmed by an independent body.

Eurocoop indicated that in terms of consumer protection a pre-clearance system for claims should be established. In terms of substantiation of health claims, Eurocoop indicated that health claims need to be supported by scientific evidence, controlled by an independent body of experts.

Other criteria mentioned by Eurocoop for making a claim were:
"- ensure that the product making the claims is of a composition, which, overall will positively contribute to a nutritionally adequate diet;
- ensure that health claims are consistent with official dietary and nutrition recommendations;
- ensure that health claims are clear, understandable and not misleading;
- health claims are formulated to take into account the need for a balanced diet;
- health claims should be sufficiently detailed to enable the consumer to evaluate the claim him/herself;
- health claims must give an overall picture of the cause and effect described in the marketing material, with particular reference to the food product in question; and
- appropriate additional information on the ingredients of the product, the percentage of the 'functional' ingredient, maximum limits, serving size, recommended amounts, etc." (Eurocoop presentation at Nutraceutical Technology Europe, 4 March 1999, see Annex 24).

As to the burden of proof, it was clear that Eurocoop believes that this should be with the maker of the claim.

BEUC stressed that it had not yet finalised its position on health claims. At this stage it felt that a pre-clearance procedure may be desirable, in order to avoid misleading claims. This should not stop a producer from bringing the new product immediately onto the market but without the claim.

The CIAA indicated that it was against a priori approval procedures, as:

- these would delay the putting on the market of a product, which was crucial for the food industry since it was a fast moving market;
- it was not possible to copyright final food product and/or the claim made; and
- industry was worried that confidentiality was not ensured during an a priori approval procedure.

In addition, as additives could only be used if they fulfilled the safety criteria set up in the EU additives legislation, and as any new ingredients had to follow the Novel Foods regulation procedure, there was no need for a prior verification. Furthermore, the CIAA felt that for the limited amount of false claims, it would be unproportional to introduce such a strict system as pre-clearance.

With regard to the burden of proof, the CIAA felt that this was not something that should be regulated by the EU. In any case, the producer would always have to have all materials available to justify the claim made.

On this issue, Eurocommerce stated that whoever uses a claim had to be able to prove it.

The European Food Law Association indicated that in its view the burden of proof should be with the maker of the claim.

On the issue of pre-clearance, EHPM argued that if a mandatory system was set up, it would establish yet another competence for an authority, which would become inflexible, potentially expensive, subjective and where probably there would be no appeal and no clear deadlines as to when an approval would be given. A notification type system, such as for foodstuffs for particular nutritional uses, was seen as a far better system.

EHPM also felt that in terms of pre-clearance it should be left to industry self-regulation. This would ensure that it was flexible and would help industry to get products onto the market as quickly as possible, whilst obviously providing the required checks.

With regard to scientific substantiation of claims, EHPM considered this an acceptable approach. However, they raised the issue that the scientific evidence could easily be subjective, lead to disagreements, as well as the necessity of undertaking clinical trials. Whilst they agreed that trials needed to be done, they could become expensive and very costly for small and medium sized enterprises.

In a similar way, EHPM felt that if there were to be a shift of the burden of proof, this would be very costly for small and medium sized enterprises.

On the issue of substantiation, the European Commission Concerted Action on Functional Foods in Europe, states in its consensus document that any claim or statement "must be based on sound scientific evidence that is both objective and appropriate". It continues to state that "it is important that the required supporting evidence should:

- be consistent in itself;
- be able to meet accepted scientific standards of statistical and biological significance
- be plausible in terms of the relationship between intervention and results;
- be provided from a number of sources, including human studies." (Scientific Concepts of Functional Foods in Europe: Consensus Document, in: British Journal of Nutrition, Volume 81 Supplement Number 1 1999, page S.24-S25, Annex 15).

On the issue of substantiation, it is also interesting to note that the Forum on Functional Food of the Council of Europe, which was held in December 1998, concluded in its recommendations that claims "needed to be supported by sound science in order to demonstrate their relevance and validity. It was underlined that messages should not mislead the consumer." (Forum on Functional Food, Proceedings, Strasbourg, Council of Europe 1-2 December 1998, p. 29, see Annex 26).

As mentioned above, Eurocommerce indicated that many manufacturers were abstaining from using ethical claims, as it was often impossible to ensure the full veracity of an ethical statement such as 'no child labour'. This was also the case for

companies that had very strict control mechanisms in place with regard to child labour.

A European Workshop on Monitoring of Codex of Conduct and Social Labels was organised in November 1998 by DG V. The aim of the workshop was to have an exchange of experience gained with codes and labels, as well as an exchange of views on monitoring of codes and labels. The workshop, in which a large number of interested parties from industry and NGOs participated, concluded that monitoring, "in the view of most participants - has to be independent and should be organised externally. It must be carried out meeting professional standards. For this reason, the accreditation of auditors and the development of methods of certification are two priority issues. The ILO could play a major role in the accreditation of certification agencies and the training of auditors. Nevertheless the input from local, national, European, and international levels must not be neglected." (European Workshop on Monitoring of Codes of Conduct and Social labels, European Commission DG V, January 1999, p. 20, see Annex 27).

V. CASE LAW

1. Nutritional Claims

We did not come across any Court cases on nutritional claims.

2. Health Claims

There exist only a few cases from the European Court of Justice that directly deal with health claims. A number of cases deal with the definition of medicinal products, in which context the issue of health claims is addressed.

A prominent example is the Ter Voort case (Case C-219/91, *Ter Voort*, 28 October 1992). Mr. Ter Voort marketed herbal teas in The Netherlands, which had been imported from South America. These herbal teas were sold without any indication of any therapeutic properties. Nevertheless, a foundation called "Stichting Nieuwe Horizon", which is also based in The Netherlands sent to consumers on request brochures describing the therapeutic or prophylactic properties of these herbal teas.

In a preliminary ruling, the ECJ was asked by the national court inter alia whether a product which has - based on current scientific knowledge - no pharmacological properties, but which is presented as having curative or preventive properties can be considered a medicine under Directive 65/65. The national court furthermore asked whether for answering this question it was determinant that the pharmacological properties were not mentioned on the product, but were sent separately in a publication either in conjunction with the sale or independently from the sale.

The ECJ based its judgement on Directive 65/65 on medicinal products. The ECJ stated that Directive 65/65 establishes two definitions of medicinal products: a definition by virtue of the presentation of the product and one by virtue of its function. The ECJ indicated that a product was a medicinal product if it falls within either of those definitions.

The ECJ concluded that "a product recommended or indicated as having prophylactic or therapeutic properties is a medicinal product within the meaning of the provisions of the first subparagraph of Article 1 (2) of Directive 65/65, even if it is generally regarded as a foodstuff and even if in the current state of scientific knowledge it has no known therapeutic effect".

The ECJ argued that Directive 65/65 was designed to "catch not only medicinal products having a genuine therapeutic or medical effect but also those which are not sufficiently effective or do not have the effect which their presentation might lead to expect, in order to preserve consumers not only from harmful or toxic medicinal products as such but also from a variety of products used instead of the proper remedies".

The ECJ also concluded that a product "whose therapeutic properties are indicated solely in a publication, such as a brochure, which is sent, at his request, to the purchaser after sale by the manufacturer or the seller of the product or by a third party - in the latter case, where the third party does not act completely independently of the manufacturer or the seller - may be categorized as a medicinal product […]".

The ECJ stated that the exercise of freedom of expression as laid down in article 10 of the European Human Rights Convention has to be measured with the objective of health protection, which is the objective of Directive 65/65. The ECJ drew attention to the fact that article 10 (2) of the European Human Rights Convention provides for the possibility to restrict the freedom of expression on public health grounds.

This ruling indicates that the ECJ considers a strict interpretation of 65/65 as a mean to protect consumers not only against toxic medicinal products, but also from other products (e.g., foodstuffs such as herbal teas) which are used instead of the proper remedies.

The ECJ came to the same conclusion in a case involving Upjohn against Farzoo Inc. (Case C-211/89, *The Upjohn Company,* 16 April 1991). Upjohn was selling in The Netherlands a lotion called 'Regaine' aimed at combating alopeica androgenetica. An identical product of the company Farzoo Inc. called 'Minoxidil' was sold in The Netherlands as a cosmetic product. Upjohn complained that this was unfair competition. It is interesting to note the part of the preliminary ruling where the ECJ analyses the wording 'presentation' used in Directive 65/65. The ECJ concludes that "le critère dit de 'présentation' retenu par le premier alinéa du texte a pour but d'appréhender non seulement les médicaments qui ont un effet thérapeutique ou médical véritable, mais également les produits qui ne seraient pas suffisamment efficaces, ou qui n'auraient pas l'effet que leur présentation permettrait d'en attendre afin de préserver les consommateurs non seulement des médicaments nocifs ou toxiques en tant que tels, mais aussi de divers produits utilisés en lieu et place des remèdes adéquates. Il en résulte que la notion de présentation d'un produit doit être interprétée de façon extensive".

Here again, the ECJ argues for a wide interpretation of Directive 65/65, in particular with regard to the term 'presentation'.

A different example involving the customs tariff classification of two vitamin preparations can be found in the Glob-Sped AG case (Case C-328/97, *Glob-Sped AG*, 10 December 1998). The company Glob-Sped AG wanted to import two vitamin C preparations as medicinal products under the Common Customs Tariff. The German customs held that the product should be classified as a food preparation. The customs authorities also held that the properties of the product (in particular the strong dose of vitamin C) were not sufficient for the product to be classified as a medicament under the Common Customs Tariff, in particular as the packaging did not contain an indication on the specific effectiveness in combating certain illnesses.

The national court asked the ECJ in a preliminary ruling inter alia whether vitamin preparations with 1000mg and 500mg of vitamin C per pill respectively and with product information stating "to build up resistance: for colds and influenza infections, […] and allergic processes" and "as a prophylactic at times of increased risk of infection" should be considered a medicinal product under the Common Customs Tariff.

The ECJ concluded that it was "undisputed that the vitamin C content of the products in question is much greater than what is necessary or recommended for general dietary purposes. Furthermore, besides assisting the immune system of the human organism to resists infections in cases of, inter alia, asthenia or severe strain, such doses of vitamin C, which the human body is incapable of making for itself, are also recommended as treatment for allergic reactions and severe traumatisms, of the kind which may result form an injury or a surgical operation, or to combat deficiency-related illnesses […]".

The ECJ, therefore, concluded that the two vitamin preparations had to be considered as medicinal products under the Common Customs Tariff.

While the Court did not directly indicate whether the claims made would be sufficient to qualify the vitamin preparations as a medicinal product, some more indications can be found in the opinion of the Advocate General, who concluded that the packaging of the products concentrates on "the products' more general effects on the body's immune system. It also refers to their traditional use as a strengthener, which use, taken on its own, would not be sufficient to qualify the products as a medicament […]".

Nevertheless, it is difficult to apply directly cases on the interpretation of the Common Customs Tariff for our research, as the ECJ concluded itself that the objectives of Directive 65/65 (public health protection and elimination of trade obstacles) are different from those of the Common Customs Tariff and that the classification of a product as a medicinal product for the purpose of Directive 65/65 was wide and could vary between Member States. The Common Customs Tariff on the other hand had to be applied in a uniform manner by all Member States (see recent Case 270/96, *Laboratoires Sarget SA*, 12 March 1998, as well as Case C-201/96, *Laboratoires de Thérapeutique Moderne*, 6 November 1997).

A more recent case that came before the ECJ is of direct interest to our study as regards substantiation of claims (Case 77/97, *Österreichische Unilever GmbH*, 28 January 1999). The preliminary ruling concerned a dispute between Unilever and

Smithkline Beecham regarding the sale of Smithkline's toothpaste 'Odol-Med 3' in Austria.

Smithkline sold the toothpaste with on-pack and television advertising stating that it helps to prevent parodontosis, provides triple protection against dental caries, plaque and parodontosis and removes or prevents the formation of tartar. Unilever argued that these claims were contrary to the Austrian cosmetic decree and the relevant article on health claims of the Austrian Food Law, as the toothpaste in question contained only one of the decay-inhibiting pharmacologically active substances listed in an annex to the Austrian cosmetic decree and none of the substances listed therein which prevent the formation of tartar or parodontosis. Unilever, therefore, considered these statements to be incorrect and misleading.

Unilever objected to Smithkline's reasoning that article 30 of the EU Treaty could be invoked, as the issue here concerned the health of consumers which was covered by the exceptions listed in article 36 of the EU treaty. Furthermore, as there existed no Community rules on the composition and content of cosmetic products, the Austrian cosmetic decree could not be regarded as being contrary to Community law. Smithkline on the other hand argued that EU Directive 76/768 on Cosmetic Products fully harmonises legislation in this area. Where a product fulfills the requirements of Directive 76/768, a Member State may not restrict its sale or marketing.

The ECJ was asked by the Handelsgericht Wien whether article 30 of the Treaty in conjunction with the Cosmetic Products Directive preclude a national provision "which, as regards advertising in connection with the marketing of cosmetic products, contains prohibitions going beyond the restrictions contained in the directive?".

The ECJ stated that Directive 76/768 completely harmonised national rules on the packaging and labelling of cosmetic products. Article 6(3) of Directive 76/768 notably forbids attributing characteristics to those products in the labelling and advertising of cosmetic products, which they do not have. The ECJ indicated that this was also aimed at "protecting human health, within the meaning of article 36 of the Treaty, in so far as misleading information regarding the characteristics of such products could affect public health". Nevertheless, measures applied under article 36 have to be proportional to the aim researched.

The ECJ then analysed in more detail the question of proportionality. Smithkline pointed out to the ECJ that the Austrian cosmetic decree would be compatible with article 6(3) of Directive 76/768, if its annex comprised all active substances which may prevent the formation of tartar of parodontosis. The ECJ stated that it was apparent from the hearing it held in the context of this legal dispute, that this was not the case.

While Austrian law foresees that manufacturers of cosmetic products which contain active substances not listed in the annex to the Austrian cosmetic decree may apply for special authorisation for the use of such substances, the ECJ argued:

"It is possible to ensure the protection of consumers, public health and fair trading by adopting measures which are less restrictive of the free movement of goods than the automatic exclusion of advertising by a system that prohibits the advertising of

substances not expressly listed in the Kosmetikverordnung [Austrian cosmetic decree]".

The ECJ concluded: "Thus, the controls exercised by the national authorities could take the form, inter alia, of an obligation requiring the manufacturer or distributor of the product in question, in the event of any uncertainty, to furnish evidence of the accuracy of the advertisements concerned, in the manner provided for by Article 6 of Council Directive 84/450/EEC […]".

While this case solely concerned a claim made on the basis of an ingredient not listed in the Austrian cosmetic decree, it seems to indicate that the ECJ considers a control system for claims as foreseen under article 6 of the Misleading Advertising Directive as a viable way of controlling claims.

The ECJ did not further define claims in this ruling, but used the wording 'statement' and 'advertising'.

There are only a few ECJ cases dealing directly with health claims. The few that have come to the Court indicate with regard to consumer protection that the ECJ is in favour of a wide interpretation of Directive 65/65 (see Annex 6), in order to protect the consumer against products used instead of adequate remedies. On the other hand, the ECJ cases seem to indicate that the Court considers a control system for claims as foreseen under article 6 of the Misleading Advertising Directive as a viable way of controlling claims. The ECJ cases do not provide much information regarding barriers to trade.

3. Ethical Claims

We have not come across any Court cases involving ethical claims.

VI. MEANS OF COMMUNICATION

Under Directive 90/496 on Nutrition Labelling (Annex 1), it is stipulated that a nutritional claim means "any representation and any advertising message" (article 1 (4) (b)). This wording suggests that it applies to all means of communication.

Under Directive 79/112 on the Labelling of Foodstuffs (Annex 2), the ban on misleading claims and the restriction of certain health-related claims shall under the Directive apply to the labelling, presentation of foodstuffs, their shape, packaging, display and advertising (see article 2 (1) and 2 (3)). This wording suggests that it applies to all means of communication.

Equally, the interdiction of certain health-related claims under Directive 89/398 on Foodstuffs for Particular Nutritional Uses (Annex 7) applies to labelling, labelling methods used, presentation and advertising (see article 6 (1)).

Directive 84/450 on Misleading Advertising Directive (Annex 5) applies to advertising. The definition of advertising used is the following:

" 'advertising' means the making of a representation in any form in connection with a trade, business, craft or profession in order to promote the supply of goods or services, including immovable property, rights and obligations" (article 2 (1)). The wording "the making of a representation in any form" would suggest that all means of communication are covered.

The specific provisions on claims made on alcoholic beverages as set out under Directive 89/552 on Television Broadcasting Activities (Annex 9) only apply to television advertising, as the scope of the Directive is confined to television broadcasting (see article 15).

VII. ANNEXES

1. Council Directive 90/496/EEC of 24 September 1990 on Nutrition Labelling for Foodstuffs
2. Council Directive 79/112/EEC of 18 December 1978 on the Approximation of the Laws of the Member States relating to the Labelling, Presentation and Advertising of Foodstuffs
3. Proposal for a European Parliament and Council Directive on the Approximation of the Laws of the Member States relating to the Labelling, Presentation and Advertising of Foodstuffs (codified version), COM (1999)113 final, 14 April 1999
4. Council Directive 84/450/EEC of 10 September 1984 relating to the Approximation of the Laws, Regulations and Administrative Provisions of the Member States concerning Misleading Advertising
5. Directive 97/55/EC of the European Parliament and of the Council of 6 October 1997 amending Directive 84/450/EEC concerning Misleading Advertising so as to include Comparative Advertising
6. Council Directive 65/65/EEC of 26 January1965 on the Approximation of Provisions laid down by Law, Regulation or Administrative Action relating to Proprietary Medicinal Products
7. Council Directive 89/398/EEC of 3 May 1989 on the Approximation of the Laws of the Member States relating to Foodstuffs intended for Particular Nutritional Uses
8. Council Directive 80/777/EEC of 15 July 1980 on the Approximation of the Laws of the Member States relating to the Exploitation and Marketing of Natural Mineral Waters
9. Council Directive 89/552/EEC of 3 October 1989 on the Coordination of Certain Provisions laid down by Law, Regulation or Administrative Action in Member States concerning the Pursuit of Television Broadcasting Activities
10. Directive 97/36/EC of the European Parliament and of the Council of 30 June 1997 amending Council Directive 89/552/EEC on the Coordination of Certain Provisions laid down by Law, Regulation or Administrative Action in Member States concerning the Pursuit of Television Broadcasting Activities
11. Codex General Standard for the Labelling of Prepackaged Foods, CODEX STAN 1-1985 (Rev. 1-1991)
12. Codex General Guidelines on Claims, CAC/GL 1-1979 (Rev. 1-1991)
13. Codex Guidelines for Use of Nutrition Claims, CAC/GL 23-1997
14. Proposed Codex Draft Recommendations for the Use of Health Claims, ALINORM 99/22A Appendix VII

15. Scientific Concepts of Functional Foods in Europe: Consensus Document, in: British Journal of Nutrition, Volume 81 Supplement Number 1 1999
16. European Parliament Resolution on the Commission Green Paper on the General Principles of Food Law in the European Union (COM(97)0176 - C4-0213/97), Minutes of 10 March 1998
17. European Parliament Resolution on EU Standards for European Enterprises operating in Developing Countries: Towards a European Code of Conduct (A4-0508/98, Minutes of 15 January 1999
18. BEUC, Consumer Priorities for the Finnish Presidency, 120/99, (attached only section on food labelling)
19. BEUC, Consumer's View on Health Claims and Regulations: European, Presentation of Kees de Winter at the Conference 'Dietary Supplements & Fortified Foods', 28th January 1998, Kensington Park Hotel, London
20. BEUC, Comments on the Commission Green Paper on the General Principles of Food Law in the European Union COM 997) 176, BEUC/314/97, 18 September 1997
21. CIAA, Code of Practice on the Use of Health Claims (draft)
22. CIAA, Claims on Nutrition and Health: Substantiation, Assessment and Monitoring Aspects, CIAA Guidelines, MIN/132./97E Final, 1 October 1997
23. CIAA, Claims on Nutrition and Health: Position Paper on the Regulatory Aspects, MIN/149/96E Final 2, Brussels 1 February 1999
24. Eurocoop, Functional Food - Consumer Policy and Protection, Speech by Caroline Naett, Secretary General Eurocoop, Nutraceutical Technology Europe, Brussels 4 March 1999
25. Eurocoop's Comments on the Commission's Green Paper on the General Principles of Food Law in the European Union, Brussels 5 September 1997
26. Council of Europe, Forum on Functional Food Proceedings, Strasbourg 1-2 December 1998 (attached is only Summary and Recommendations)
27. European Workshop on Monitoring of Codes of Conduct and Social Labels, Brussels 25 November 1998, European Commission DG V, January 1999
28. EFTA Fair Trade Guidelines, December 1995
29. Fair Trade Labelling Organizations International, Criteria for Coffee, Tea, Cocoa, Honey, Sugar, Orange Juice, Banana
30. European Commission - DG V/D, European Social Dialogue, Special Edition: Codes of Conduct and Social Labels, Ethical Consumption and Production, May 1999
31. Council Directive 76/768/EEC of 27 July 1976 on the Approximation of the Laws of the Member States relating to Cosmetic Products

Case Law:

1. Case C-219/91, *Ter Voort*, 28 October 1992
2. Case C-211/89, *The Upjohn Company,* 16 April 1991
3. Case C-328/97, *Glob-Sped AG*, 10 December 1998
4. Case 270/96, *Laboratoires Sarget SA*, 12 March 1998
5. Case C-201/96, *Laboratoires de Thérapeutique Moderne*, 6 November 1997
6. Case 77/97, *Österreichische Unilever GmbH*, 28 January 1999

VIII. CONTACT DATABASE

B. AUSTRIA

I. EXECUTIVE ANALYSIS

A. INTRODUCTION

This study on nutritional, health and ethical claims was generally well received by all interested parties in Austria. Those who participated in the study were pleased to see that DG XXIV was looking at this issue.

B. MEMBER STATE POLICY

1. Nutritional Claims

The definition of a nutritional claim is a direct transposition of EU law. Legislators, industry and consumers are generally satisfied with the current legislation on nutritional claims. However, it was pointed out that a revision would be useful to include some substances (e.g. potassium), which are not listed in the EU Directive on Nutrition Labelling.

2. Health Claims

With regard to health claims, these are forbidden under the national implementing legislation of Directive 79/112. Nevertheless, Austrian legislation is much stricter than Directive 79/112, as it also forbids references relating to physiological effects, especially with regards to the preservation of youth, the prevention of the ageing process, and the preservation of health.

Since the Foodstuffs Inspection Service is increasingly notified of borderline cases, (where it is not clear whether these health claims are forbidden or not) the Federal Chancellery published in June 1999 an Enactment, which provides a list of examples of claims which are allowed and not allowed. The Enactment is aimed at providing clearer guidelines to food inspectors.

3. Ethical Claims

The issue of ethical claims has received little attention to date in Austria. There exist no legislation or voluntary agreements on ethical claims. Nor are the authorities envisaging any legislation on ethical claims. Consumer associations indicated that ethical labels do not so far have a great influence on the shopping habits of Austrian consumers.

C. VOLUNTARY CODES OF PRACTICE

Although there exists no voluntary agreement on nutritional or health claims, an industry voluntary agreement was set up in September 1995 which was geared at protecting Austrian consumers from misleading advertising. As such, it indirectly impacts on claims. This voluntary agreement also contains a section on health, which

basically reproduces the relevant provisions of the Austrian food law on health claims. This voluntary agreement is a self-restraining agreement, i.e. whereby industry agrees not to make certain claims in advertising. The authorities consider this voluntary agreement to be an element of consumer protection and an additional support to existing legal provisions.

D. VERIFICATION SYSTEMS

With regard to the substantiation of claims, in the case of nutritional and health claims, Austrian authorities require manufacturers to send in information on the composition of the product and a copy of the label. In addition, for health claims, (which are complex or could be controversial) an explanation must be included. There are no suggested or mandatory formats or guidelines for supplying the information. However, the Federal Chancellery indicated that if more qualitative support material is provided for substantiating a claim, the authorisation process will be easier and faster.

There is no legal timeframe for the approval procedure of claims. In practice, the duration varies considerably according to the type of claim and the quality of the information provided. It can take between 6 months and 2 years. On average a decision is made within 3 to 6 months. On average 1000 to 2000 authorisations are requested per year. Claims for which an authorisation is requested most frequently are claims in line with current trends (i.e., staying fit, losing weight), such as "reduces weight" or "encourages digestion".

The Federal Chancellery can withdraw a manufacturer's authorisation for the use of a certain claim, if it considers that the grounds on which the claim was originally based is no longer valid.

As to post-clearance, the supervision of the products on the market is exercised at the level of the regions. There are nine regional bodies in charge of supervision and analysis of foodstuffs.

If the authorities start an investigation or lodge a complaint, the burden of proof is with the manufacturer. If a party starts a legal procedure on the basis of the law on unfair competition, the burden of proof is with the plaintiff. The penalties can range between 100,000 shillings (approx EUR 7 267) and 200,000 shillings (approx. EUR 14 534) for fines imposed by the authorities on the basis of the food law. Following a procedure under the law on unfair competition, products can be confiscated and compensation as well as the publication of the judgement can be asked for by the court.

E. MEANS OF COMMUNICATION

Austrian legislation does not differentiate between means of communication as it does not differentiate between labelling and advertising. Legislation on nutritional and health claims applies to all forms of communication. It has, however, been pointed out on several occasions and by all parties (in particular the consumer association) that direct mail and the Internet are very problematic.

F. CONSUMER PROTECTION

The Federal Chancellery acknowledges that whilst certain health claims should be allowed, there was a need to protect consumers from exaggerated or inexact claims. Despite the fact that the authorisation procedure for health claims is time consuming, the authorities consider it to be an effective means of consumer protection.

The Austrian consumer association felt that, in spite of the authorisation procedure, there were still cases where the authorities were allowing misleading claims. An example provided concerned "Schonkaffee" ('light coffee' or 'soothing coffee') where the 'soothing' element was difficult to see and may lead to the assumption that this type of coffee "is good for you".

G. BARRIERS TO TRADE

Industry indicated that, as Austrian legislation on health claims is very restrictive to the point that some industry representatives claim that Austrian rules do not conform to EU law and, therefore, create barriers to trade. They argue that companies cannot sell their products across the EU in a similar manner. Such barriers seem to exist in particular between Austria and Germany, due to the use of the same language.

Industry felt that Austria's authorisation procedure for health claims had created a complex system with long delays for the approval of products (up to two years). This created further barriers to trade.

H. CASE LAW

There are a number of Austrian court cases with regard to health claims. These indicate that Austrian courts generally follow a very strict interpretation of health claims.

I. STAKEHOLDER ANALYSIS

Austria is one of the few countries in the EU that has established an authorisation system for the use of nutritional and health claims. While this system is considered too 'heavy' by industry, the authorities and consumer associations seem to favour such a system. They believe it constitutes a rather good mechanism to ensure consumer protection. How far such a system complies with the principle of the free movement of goods is yet to be seen. A complaint has been submitted in 1998 with DG XV.

In conclusion, the positions of the main stakeholders are:

1. Government Authorities

- On nutritional claims, authorities are in general satisfied with the current legislation.

- On health claims, the authorities concede that certain health claims should be allowed. However, in order to protect consumers, the Austrian system of pre-clearance should be applied.

2. Consumer Organisations

- Consumers support the system of pre-clearance for claims and are, in general, against allowing health claims.

3. Industry

- With regard to nutritional claims, industry does in general not see a need for review (except for adding some ingredients currently not covered by nutrition labelling).

- Industry considers Austrian legislation to be too strict. Physiological claims should in its view be allowed.

- On ethical claims, there is no position. But in general, all interested parties do not see a need for legislation.

* * *

II. MEMBER STATE POLICY

A. DEFINITION OF CLAIMS

1. Nutritional Claims

According to §3(2) of the Austrian law on nutritional labelling (Nährwertkennzeichnung von Lebensmitteln, NMKV, 29 December 1995, BGBI. No. 896/1995, see Annex I) nutritional claims are defined as:

"Statements, depictions or messages which, at the time of marketing of a foodstuff, suggest or directly state that the foodstuff has particular nutritional characteristics because it delivers / does not deliver energy (in higher or reduced doses) or because it includes / does not include nutrients (in higher or reduced measure). Statements or claims about the alcohol content of a foodstuff are not considered to be nutritional claims according to this law."

The law does not refer to drinking water, water from natural springs or natural mineral water as well as claims regulated by other legal acts (§1(2.1), NMKV 1995).

The NMKV is a direct transposition of the EU Directive 90/496/EC on Nutrition Labelling of Foodstuffs.

2. Health Claims

According to §9(1) of the Austrian foodstuff legislation (Lebensmittelgesetz, LMG, 23 January 1975, BGBI. No. 86/1975, last adaptation BGBI No. 372/1998, see Annex II) all health claims are forbidden on foodstuffs if they fall under the following definition:

"Claims referring to the prevention, relief or cure of diseases or symptoms, or relating to physiological or pharmacological effects or the impression of causing such effects, especially with regards to the preservation of youth or the prevention of the ageing process as well as the loss of weight or the preservation of health. Health claims are also regarded as recommendations from doctors, medical reports and tails about sickness. Furthermore, health-related, pictorial or stylised representations of organs of the human body, portrayals of members of the medical professions or health resorts/ spas as well as other depictions relating to health are considered as unacceptable health claims."

The Enactment No.1 of the Federal Chancellery of 2 June 1999 (GZ AV 31.901/31-VI/B/12/99, see Annex VI) gives a more detailed definition of health claims and distinguishes between claims that are directly health related and may not be used on foodstuffs under any circumstances and claims that refer to the well-being of people and may be used with or in some cases without going though the approval procedure. The Federal Chancellery established this Enactment as a point of reference for the foodstuffs inspection in Austria on the request of interested parties.

The Enactment defines health claims as generally inadmissible if they are:

- misleading for consumers

The Enactment states that in order to determine whether a claim on the label of a foodstuff is misleading, the national court has to consider how an alert and understanding average consumer with an average knowledge would understand the claim in question (ECJ case law, C-210/96). Examples are given (see section II.D).

- "disease-related" (krankheitsbezogen) or give the impression of having an effect in this direction. (Natural mineral water and dietetic foodstuffs are excluded from this definition). Examples are given (see section II.D).

- The Enactment defines health claims as admissible following approval according to §9(3) LMG 1975 if they are claims, which are generally, considered to be true and refer to the function or effect of substances in the human body. Examples are given (see section II.D).

- The Enactment also gives examples for claims that may be used without approval as they should not be considered to be health related according to the definition given in §9 LMG 1975. Examples are given (see section II.D).

The LMG follows article 2§2 of the EU Directive 79/112/EC on labelling of foodstuffs as well as the Codex Alimentarius (which both states that disease related claims are not allowed on foodstuffs). Compared with the proposed Codex draft recommendations for the use of health-claims, Austrian legislation clearly does not allow disease risk reduction claims and even the use of enhanced function claims seems to be very limited.

3. Ethical Claims

There are no definitions/explanations for ethical claims in Austria.

B. LEGISLATION IN PLACE

1. Nutritional Claims

The EU Directive 90/496/EEC on Nutrition Labelling for Foodstuffs of 24 September 1990 was transposed into Austrian law by NMKV 1995. NMKV 1995 implements the requirements of 90/496/EEC in all essential respects (i.e. definitions, information to be supplied, form of declaration, etc.). However, it does not include a definition of dietary fibre.

Nutritional labelling is voluntary under NMKV 1995 but it must comply with legal provisions if it is used. Furthermore, as explained above, the law does not apply to drinking water, water from natural springs or natural mineral water as well as claims regulated by other legal acts (§1(2.1), NMKV 1995).

2. Health Claims

The making of claims on product labels is regulated by the Austrian law on the labelling of foodstuffs (Lebensmittelkennzeichnungsverordnung, LMKV, 30 January 1993, BGBI No. 72/1993, see Annex III). For the definition of health claims and the implementation of the relevant provisions of Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer, Austrian legislation is regulated by LMG 1975.

Furthermore, the Directive 89/398/EEC on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses (PARNUTS) has been transposed into Austrian legislation by LMG 1975.

Health claims are defined by §9 LMG 1975 in a broad sense as comprising any information, in writing or in pictorial form, which refers to health related or physiological effects (see also detailed definition in Section II.A.2). Health claims are forbidden unless the Federal Chancellery has granted authorisation.

Derogations apply for 'traditional health claims' if they do not mislead the consumer. In practice, a 'traditional health claim' must have been in use for at least one generation before 1975. A further derogation is given to 'truthful' claims about the dietetic purpose of a dietetic foodstuff (§17(1.b) LMG 1975).

3. Ethical Claims

There is no legislation on ethical claims at either EU or Austrian national level.

C. EXISTING PROHIBITIONS, RESTRICTIONS AND EXEMPTIONS

1. Nutritional Claims

The NMKV 1995 sets out very clearly, which claims may be made and which claims cannot be made for those ingredients covered by legislation. The existing restrictions and exemptions relate to ingredients not covered by the NMKV 1995. It is unclear to all interested parties why these ingredients were left out. However, the fact of the matter is that they do lead to restrictions. An example, which was put forward, are nutritional claims about the Potassium-content of a foodstuff.

2. Health Claims

Existing prohibitions, restrictions and exemptions for health claims are detailed in the Enactment No.1 of the Federal Chancellery of 2 June 1999.

For health claims that are generally inadmissible because they are misleading, the Enactment gives the following examples:

- "Gesundheitstrunk" (health drink)
- "Ein täglicher Beitrag zur Gesundheit…" (A daily contribution to your health)
- "…für gesunde Fingernägel und Haare…" (for healthy finger nails and hair)

- "Das gesunde Plus" (The healthy extra)
- "…ist hervorragend zum Masseaufbau geeignet…" (is very well suited for building up your muscular volume)
- "…unterstützt Betacarotin die natürliche Hautbräunung,…" (Beta-carotene supports the body's natural tanning process)
- "regt den Stoffwechsel an, unterstützt die Verdauung" (encourages the digestive system, supports digestion)
- "entwässernd" (dehydrating)
- "…enthält natürliche Flavonoide. Diese können bei frühzeitigen Alterserscheinungen helfen, geistige Erfrischung zu schaffen" (contains natural flavonoides. In case of signs of early ageing, these can help in creating spiritual freshness)
- "…kann es sinnvoll sein, die tägliche Nahrung mit Q10 zu ergänzen, damit sie ihre volle Leistung erbringen können." (it can make sense to add Q10 to your daily food in order to be able to deliver your full potential)

For health claims that are generally inadmissible because they are disease-related, the Enactment gives the following examples:

- "…heilt Magenkrebs" (cures cancer of the stomach)
- "…beugt dem Herzinfarkt vor" (prevents heart attacks)
- "…gegen Schlaganfall" (against strokes)
- "…schützt vor Osteoporose" (protects against osteoporosis)
- "Zur Stärkung der Blasenfunktion" (for strengthening the functioning of the bladder)
- "XY senkt den Cholesterinspiegel" (XY reduces the cholesterol level)
- "Nährstoffe für…"iVm Herz, Kreislauf, Gedächtnis,…" (Nutrient for…heart, circulation, memory)
- "unterstützt Nerven, Kreislauf, Verdauungs- und Immunsystem" (supports nerves, circulation, digestive and immune system)
- "Hilfe bei Durchfallerkrankungen" (helps relieve constipation)

For health claims considered as admissible following approval, the following examples are given in the Enactment:

- "Die Inhaltsstoffe der Kürbiskerne wirken positiv auf Blase und Prostata" (The components of pumpkin seeds have a positive effect on the bladder and the prostate).
- "Levithin ist ein wichtiger Baustein der Zellen, besonders der Zellmembran und des Nervengewebes. Außerdem enthält es die … Linolsäure, die beim Transport des Cholesterins benötigt wird" (Lecithin is an important element of cells, specially of the cell-membrane and of the nerve-texture. It also contains Linolacid which is needed for the transport of cholesterol)
- "Zink nützt Haut, Haaren und Nägeln, es ist ein wichtiges Spurenelement im Insulinstoffwechsel" (Zinc is good for skin, hair and nails, it is an important trace element for the insulin-metabolism)
- "Die Polyphenole wirken als Antioxidantien und unterstützen die körpereigene Abwehrkräfte" (Polyphenols act as antioxidants and support the body's resistance ability)

- "Omega-3-Fettsäuren sind mehrfach ungesättigt und haben einen positiven Einfluß auf den Stoffwechsel" (Omega-3-fatty acids are polyunsaturated and have a positive influence on fatty-metabolism)
- "Vitamin E ist wichtig für die Funktionsfähigkeit von Muskulatur, Nervensystem und Fortpflanzungsorganen" (Vitamin E is important for the muscles functioning, nerve-system and reproductive organs)
- "Calcium gehört zu den Mineralstoffen, die der Körper zur Härtung und zum Aufbau von Knochen, Nägeln und Zähnen benötigt" (Calcium is one of the minerals which the body needs for strengthening and for growth of bones, nails and teeth)
- "Betacarotin hat die … Fähigkeit durch UV-Strahlung aktivierte, zellschädigende Substanzen, sogenannte "Freie Radikale", abzufangen und zu neutralisieren" (ß-Carotene has the ability to catch and to neutralise the so-called “Free-Radicals” which contain through UV-rays activated cell-damaging substances)
- "Die ausreichende Versorgung mit Kieselerde erhält das Bindegewebe, die Nägel, Haut und Haare elastisch und widerstandsfähig" (Connective tissue, nails, skin and hair remain elastic and resistant if there is an adequate supply of siliceous earth)
- "Bioflavonoide können doe negativen Einflüsse von Oxidantien auf die Gefäße vermeiden" (Bioflavonoids can avoid the negative influences of oxidants on the vessels)
- "Die probiotischen Kulturen unterstützen bei regelmäßigem Genuß das Gleichgewicht der Darmflora, beinflussen den Stoffwechsel poitiv und stärken die natürlichen Abwehrkräfte des Körpers" (The pro-biotic cultures support, if regularly consumed, the balance of intestinal bacteria, positively influence the metabolism and strengthen the body’s natural resistance)

For claims that may be used without approval procedure, the following examples are given in the Enactment:

- "Für Diabetiker geeignet" (suitable for diabetics)
- "(apetit)anregend" (stimulates (the appetite))
- "schmackhaft" (tasty)
- "leicht verdaulich" (easily digestible/easy to digest)
- "belebend" (invigorating)
- "bekömmlich" (digestible)
- "cholesterinfrei" (free of cholesterol)
- "kalorienarm" (low in calories)
- "wohltuend" (agreeable/does good)
- "vitalisierend" (vitalizing)
- "für Wohlbefinden" (for well-being)
- "zur Unterstützung bei geistiger Beanspruchung" (for support during demanding mental exercises)
- "zur Kräftigung" (for fortification)
- "für Energie" (for energy)
- "für Raucher" (for smokers)

In addition "harmless" and non-deceptive advertising such as "power drink" or "stimulate the senses" are given as examples of what is allowed.

3. Ethical Claims

There are no existing prohibitions, restrictions and exemptions for ethical claims in Austria.

D. POLICY DEVELOPMENTS AND STAKEHOLDERS' POSITIONS

1. Nutritional Claims

Policy thinking in Austria is currently focussed on health claims.

Legislators, industry and consumers are generally satisfied with nutritional claims legislation as it currently exists since it is well defined by the Austrian law on nutritional labelling (NMKV 1995).

The NMKV 1995 does have some small deficiencies because the value of allowed content is sometimes not given and certain nutritional ingredients are not included (e.g., potassium). This can lead to minor problems of interpretation with regards to ingredients not directly covered by nutritional labelling legislation (i.e., Austrian and EU legislation, as the EU directive 90/496 has been transposed 1:1 into Austrian legislation, NMKV 1995). When such difficulties arise, e.g. "mit rechtsdrehender Milchsäure" (in this case it was unsure whether such a claim could be used or should be prohibited as it was not covered by nutritional labelling legislation), Austrian authorities have very often taken the issue to the EU level. They have done this via their Permanent Representation in the EU and through discussions with colleagues from other Member States (in the case of the given example it was decided, following an exchange of views, that the claim should be forbidden).

Furthermore, foodstuffs destined for human consumption but without any nutritional value (e.g. chewing gum or gelatine products) referred to as "Verzehrprodukte" (definition in §3 LMG 1975) are legally excluded from the NMKV 1995, but nevertheless follow the nutritional labelling law.

2. Health Claims

According to the Federal Chancellery, the LMG 1975 as well as the LMKV 1993 are a good basis on which the use of health claims in Austria can rest. The ministry is of the opinion that the use of certain health claims should be allowed but that there is a real need to protect consumers from exaggerated or inexact claims made by manufacturers.

According to industry, the LMG 1975 is too broad as it includes under health claims both physiological and disease related claims. It believes that there should be some differentiation.

a. Ministries

Despite the pre-clearance system, legislation on health claims does leave some grey area as it is not always necessarily clear from the LMG 1975, which claims should be

allowed and which claims should not. The Foodstuffs Inspection has to be increasingly notified of borderline cases. At present there are about 100 of these cases a year. The Federal Chancellery, therefore, recently decided to issue an Enactment (Enactment No. 1, 2 June 1999) in order to provide clearer guidelines to the food inspectors and inspections when evaluating claims. The Enactment is considered to add to the LMG 1975 and to help establish more uniform procedures between the Austrian Länder for the use of claims.

Barriers to trade exist in cases where a claim made on a product marketed in both Germany and Austria (which use the same packaging as the same language is being used in both countries) contains a health claim which is allowed in Germany, but not allowed in Austria, e.g. "gesund" (healthy). A typical product where this is the case is "Jodsaltz" (iodine containing salt) which is marketed in Germany with the claim "gesünder durch Jodsaltz" (healthier because of iodine-containing salt). This is not allowed in Austria as - unlike Germany - enough iodine is contained in the natural environment and the claim is, therefore, unsubstantiated.

As the NMKV 1995 does not take account of certain nutritional ingredients, Austrian authorities did mention that it would be useful to revise the legislation in the near future to take account of these missing elements.

b. Industry

Industry stressed that Austrian legislation for health claims is very restrictive to the point where some industry protagonists claim that Austrian rules do not conform to EU law (see in particular Christian Hauer, "Österreichisches Lebensmittelrecht und EU", pp. 79-81, Annex IX; and Christian Hauer, "Verbot gesundheitsbezogener Angaben (§9 LMG 1975) und Gemeinschaftsrecht", Ernährung/Nutrition, Vol. 23, No. 3 1999, Annex X).

This situation creates barriers to trade, as companies cannot sell their products across the whole EU in a similar manner because Austria is much more restrictive than other EU Member States in the use of health claims. This causes a restriction in the free movement of goods).

c. Consumers

According to the consumers, one of the main problems of Austrian legislation on health claims is that it is not restrictive enough and that there are still cases in which claims are being allowed by the authorities which are misleading. An example given was "cholesterol free rape-seed oil". Here it was difficult to prove whether the product is really free of the ingredient and what this means for the consumer. Another example was "Schonkaffee" ('light coffee' or 'soothing coffee') where the 'light' or 'soothing' element is difficult to see and may lead to the assumption that this type of coffee "is good for you".

3. Ethical Claims

Ethical claims are not considered to be a high priority. There is no legislation in Austria on ethical claims and there are no attempts by the government to propose such

legislation. Nor are there any other interest representations calling for legislation in this field to date.

Consumer associations have informed us that ethical labels do so far not have a great influence on the shopping habits of Austrian consumers.

III. VOLUNTARY INSTRUMENTS

A. VOLUNTARY INSTRUMENTS IN PLACE

1. Nutritional Claims

There are no voluntary instruments in place in Austria, which regulate the use of nutritional claims. The use of nutritional claims is solely regulated by NMKV 1995.

2. Health Claims

There are no voluntary instruments in place in Austria regulating the use of health claims on product labels as this is regulated by LMG 1975 and LMKV 1993.

There is, however, an industry voluntary agreement ("Der Österreichische Selbstbeschränkungskodex") of 28 September 1995 geared at protecting Austrian consumers from misleading advertising (see Annex VIII), which indirectly impacts on claims. It is a self-restraining agreement, i.e. whereby industry agrees not to make certain claims in advertising. It was established by the Austrian Advertising Council (Österreichischer Werberat) located within the Austrian Association for Advertising and Marketing Communications (Fachverband Werbung und Marktkommunikation) and includes a section on "health" (Gesundheit).

The Austrian Voluntary Agreement is divided into two parts. The first part "grundsätzliche Verhaltensregeln" (fundamental rules of conduct) deals with guidelines for sensitive areas (ethics, violence, health, security and environment) and is considered to be the centrepiece of the agreement. The second part "spezielle Verhaltensregeln" (specific rules of conduct) deals with areas that have received particular attention over time at national and international level and, therefore, need specific rules.

3. Ethical Claims

There are no voluntary agreements in Austria on the use of ethical claims.

B. DEFINITIONS USED IN THE VOLUNTARY INSTRUMENTS

1. Nutritional Claims

Not applicable.

2. Health Claims

The definition used in the voluntary agreement is very similar to the definition used in §9 LMG 1975. Section 1.4, point 5.1 of the Austrian voluntary agreement refers to the use of health claims. It says:

"Claims which refer to physiological or pharmacological effects and give the impression to the consumer that the product which is being advertised preserves the health, reduces or reverses the ageing process, reduces body weight without a change in the way of life, has a dietetic effect or a similar effect should not be made" (literal translation, see annex VIII for original text).

Otherwise, the agreement mainly refers to the prevention of misleading claims or pictorial representations. In particular, section 1.4, point 5 generally states that:

"Advertising of health should not be misleading"

Regarding pictorial representations, there is no direct relation in the text between health claims and pictorial representations, but the use of such representations should generally be avoided according to the agreement in general and according to section 1.4 in relation to health.

3. Ethical Claims

Not applicable

C. EXISTING PROHIBITIONS, RESTRICTIONS AND EXEMPTIONS

Not applicable.

D. VOLUNTARY INSTRUMENTS ACCEPTED/RECOGNISED BY THE AUTHORITIES

The Austrian Voluntary Agreement states in its introduction that it is an important element for consumer protection against misleading advertising. Furthermore, 'the self-regulatory mechanisms of the advertising sector should oversee and correct erroneous developments around the legal provisions'. Austria is described as a country with a rather well developed system for consumer protection and the voluntary agreement should add to that, in particular with regards to more sensitive areas.

1. Nutritional Claims

Not applicable.

2. Health Claims

The voluntary agreement is accepted by the authorities as an element of consumer protection and an addition to existing legal provisions.

3. Ethical Claims

Not applicable.

IV. VERIFICATION SYSTEMS

A. CRITERIA FOR SUBSTANTIATING CLAIMS

1. Nutritional Claims

Approval for the use of nutritional claims needs to be given by the Austrian Federal Chancellery prior to marketing a product. In order to assess the accuracy of claims companies must submit, according to LMG 1975, information to the authorities on the substances used when manufacturing the product and a copy of the label to be used. Manufacturers and importers may also be requested to supply additional information on the composition of the product and the way it is prepared if this is necessary for reasons of public health protection, and protection against fraud.

There are no suggested or mandatory formats or guidelines as to how the information should be supplied.

2. Health Claims

Approval for the use of health claims on foodstuffs needs to be given according to §9(3) LMG 1975 by the Federal Chancellery. In order to assess the accuracy of a claim the manufacturer must send in information on the composition of the product and a copy of the label to be used. The Federal Chancellery also pointed out that if the claim is complex or could be controversial, an explanation must be included.

As for nutritional claims, there are no suggested or mandatory formats or guidelines for supplying the information. However, the Federal Chancellery pointed out that if more qualitative support material is given for substantiating a claim, the process will be easier and faster. Companies usually recognise this and send in the right type of information.

The Federal Chancellery takes all information supplied into account when it makes its decision, including references to websites.

3. Ethical Claims

Not applicable.

B. LEGAL/ADMINISTRATIVE SYSTEMS FOR VERIFYING CLAIMS

1. Pre-Clearance Rules/Guidelines

See Section IV.A (above).

There is no legal timeframe. In practice, the duration of the approval procedure varies considerably according to the type of claim and the quality of the information provided. It can take between 6 months and 2 years. On average a decision is made within 3-6 months.

The Federal Chancellery can also withdraw a manufacturer's authorisation for the use of a certain claim if it considers that the grounds on which the claim was originally based are no longer valid (see point 2 below).

2. Post-Clearance Rules/Guidelines

The supervision of the products on the market is exercised at the level of the regions (Länder). There are nine regional bodies in charge of supervision and analysis of foodstuffs (Lebensmittelaufsichten) with a total of 260 staff. Each region has one Executive Officer (Landeshauptmann) who is in charge of the supervisory body. The Executive Officers report to the Federal Chancellery's Food Surveillance Authority.

The *Landeshauptmänner* take samples of products and their advertising and these are transferred to the regional supervisory body for analysis on their composition, labelling and advertising claims. All information supplied with or in vicinity of the product is also analysed. About 150,000 samples are taken each year and of these about 41,000 are analysed.

If a product is not in line with the relevant provisions for claims a negative report is sent to the Food Surveillance Authority which lodges a complaint with the High Administrative Court (Verwaltungsgericht), which is an obligatory process according to §44 LMG 1975. In principle, any person working for the surveillance of foodstuffs in Austria can lodge this type of complaint.

Competitors and social partners (but, at present, not consumer associations) can also start court proceedings on the basis of misleading advertising in order to take the product off the market or to claim compensation under the law on unfair competition (Bundesgesetz gegen den unlauteren Wettbewerb, UWG, 1984, BGBI No. 448/1988, last modified by BGBI 422/1994, see Annex IV). The UWG 1984 transposes the EU Directive 84/450/EEC on the approximation of the laws, regulations and administrative provisions of the Member States concerning misleading advertising.

The UWG is being modified at the moment to also offer the Austrian consumer association, the VKI (Verein für Konsumenteninformation), the possibility to start court proceedings on the basis of the misleading advertising provisions (modification of §14(1), see annex IV). The UWG is being modified in order to implement the Directives 97/7/EEC and 98/27/EEC on consumer protection.

The proposed modification of UWG 1984 has been approved by the Austrian Council of Ministers. However, it still needs to be passed through Parliament, which could still be done in this legislature, according to the VKI. The VKI also mentioned that there are not very many cases started under UWG 1984. This is because only a few dare to do so and the proceedings can take between 2 and 3 years.

Each of the most recent judgements of the High Administrative Court (March 1999) cost the losing party 4,565 shillings (approx. EUR 331).

According to the authorities, the pre-clearance procedure for claims (§9 LMG 1975) is somewhat inconvenient. This is because it is very time consuming since every claim has to be examined on its own merits (see section IV). Nevertheless, the Austrian authorities consider it very useful and necessary as it guarantees to a very large extent that claims made by manufacturers are as close to the truth as possible.

In industry's view, the pre-clearance system of §9 LMG 1975 does too much for consumer protection and leaves industry behind with a complex system of long delays for the approval of products (up to two years). In industry's opinion, a delay of maximum 6 months should be allowed.

Furthermore, there is no overview of what type of claims has been allowed and what type of claims has not been allowed, which makes the current system unclear. It would be beneficial to have a system, which is more transparent as to the reasons why certain claims were allowed on particular products. This would make it possible to find a way of speeding-up the approval of claims that already exist for similar products.

An issue, which is very important for the consumer association is that they do not have any means of taking legal action at present where they would consider that legal action is required because of a misleading claim. This leads, in their opinion, to a lack of consumer protection and a lack of input from an important actor in society. It was, however, also pointed out that the law against unfair competition (UWG 1984) is currently being revised to give consumers the right to take legal action.

C. LEGAL PERSONS ENTITLED TO TAKE LEGAL ACTION

Currently, the authorities dealing with the supervision of foodstuffs, competitors and social partners (except consumer associations) may take legal action according to UWG 1984.

D. BURDEN OF PROOF

The burden of proof is always with the manufacturer or importer when the claim is sent to the Federal Chancellery. Decisions are based on the information supplied by the manufacturer or importer in question.

If the authorities start an investigation or lodge a complaint, the burden of proof is with the manufacturer. If a party starts a legal procedure on the basis of unfair competition (UWG 1984), the burden of proof is with the plaintiff.

E. APPLICABLE PENALTIES

The LMG 1975 foresees administrative and judicial penalties. Penalties can be of a maximum amount of 100,000 shillings (aprox. EUR 7 267), and a repetition can entail a fine of up to 200,000 shillings (EUR 14 534).

Following a procedure under the UWG, products can be confiscated and compensation as well as the publication of the judgement can be asked by the court

V. CASE LAW

1. Nutritional Claims

No case law on nutritional claims has been brought o our attention.

2. Health Claims

We have been informed about the following cases by industry:

- Decision of the Verwaltungsgerichtshof, 30 January 1979
  The product in this case was coffee labelled with the claim "Schonkaffee", meaning that it is free from unwelcome stimulating/bitter characteristics and is, therefore, a pleasure for many sensitive stomachs ("mit schonender Wirkung"). The administration had considered that such a claim was misleading. However, the highest administrative court overruled this decision.

- Decision of the Verwaltungsgerichtshof, 12 May 1980
  The product, fruit candy tablets, was considered by the administration not to be a foodstuff but a medical product that should be notified as a pharmaceutical (under the medical products law, Arzneimittelgesetz, AMG, 2 March 1983, BGBI No.185/1983, last amended by BGBI No. 78/1998, see Annex V). The administration based its decision on the Vitamin C content of the product. The highest administrative court overruled this decision, confirming that upon request the administration should allow health claims that are not consumer misleading. Therefore, foodstuffs can also carry claims stating that they can have healing benefits without them being defined as pharmaceutical products.

- Decision of the Verwaltungsgerichtshof, 14 January 1985
  The product, mint-hops syrup, was not allowed to be labelled with the claim that it was 'relaxing the nerves and stimulating the readiness to sleep'. It considered the product under those circumstances to be a medical product and not a foodstuff. The highest administrative court confirmed this decision.

- Decisions (3) of the Verwaltungsgerichtshof, 22 March 1999 (see annex VII)

  Three cases were decided on 22 March 1999 where the administration had decided that certain products, to be registered as foodstuffs (more precisely as 'Verzehrprodukte'), could not be allowed onto the Austrian market - although already marketed in Germany - because of health claims which are inadmissible

according to §9 LMG 1975. In all three cases the highest administrative court confirmed the decision.

In all of these cases, it was also claimed that the Austrian procedure for registering products was too long and not easily accessible and, therefore, constituted a barrier to trade (free movement of goods) within the EU as these products were already being sold in Germany with the same label. The highest administrative court rejected these arguments, saying that the delay was reasonable for the claims being made and, more importantly, that the refusal by the Austrian authorities does not constitute a barrier to intra-EU trade. Rather the court argued that it guarantees the protection of consumers and public health from misleading claims/advertising.

- Procedure about Free Movement of Goods with the European Commission DGXV

A procedure was initiated with the European Commission's DGXV (No. 98/4739) regarding difficulties for marketing foodstuffs in Austria because of §9 LMG 1975 and these difficulties constituting a barrier to intra-EU trade and therefore going against the principle of free movement of goods.

3. Ethical Claims

There is no case law in Austria on the use of ethical claims.

VI. MEANS OF COMMUNICATION

Austrian legislation does not differentiate between means of communication as it does not differentiate between labelling and advertising. Legislation on nutritional and health claims applies to all forms of communication.

It has, however, been pointed out on several occasions and by all parties (in particular the consumer association) that direct mail and the Internet are very problematic. It is almost impossible to track the sort of claims made on the Internet. Furthermore, products sold in other markets where health claims are allowed which are prohibited in Austria can enter the country via direct mail order services (although not in large quantities).

VII. STATISTICS ON CLAIMS

There are no statistics available in Austria with regards to the frequency of use and types of nutritional, health or ethical claims.

However, the Federal Chancellery informed us that the claims for which an authorisation is requested most frequently are claims in line with current trends (i.e. staying fit, losing weight) such as "reduces weight" or "encourages digestion".

Furthermore, on average 1000-2000 authorisations are requested per year and about two-thirds are granted after modification (which is often substantial).

VIII. ANNEXES

I. Nährwertkennzeichnung von Lebensmitteln, NMKV 1995
II. Lebensmittelgesetz, LMG 1975
III. Lebensmittelkennzeichnungsverordnung, LMKV 1993
IV. Bundesgesetz gegen den unlauteren Wettbewerb, UWG 1984, and proposed draft revision
V. Arzneimittelgesetz, AMG, 1983
VI. Enactment No. 1 of the federal Chancellery, 2 June 1999
VII. Cases from the Verwaltungsgerichtshof, 22 March 1999
VIII. Voluntary Agreement, "Der Österreichische Selbstbeschränkungskodex", 28 September 1995
IX. Christian Hauer, "Österreichisches Lebensmittelrecht und EU"
X. Christian Hauer, "Verbot gesundheitsbezogener Angaben und Gemeinschaftsrecht", Ernährung/Nutrition, Vol. 23, No. 3, 1999

IX. DATABASE OF CONTACTS

C. BELGIUM

I. EXECUTIVE ANALYSIS

A. INTRODUCTION

The study was well received by all interested parties, except for the Belgium consumer association 'Test Achats/Testaankoop', which was not willing to participate in the study. Due to the dioxin crisis, it was difficult to get into contact with the Belgium administration.

B. MEMBER STATE POLICY

1. Nutritional Claims

The definition of a nutritional claim is the same as defined in EU law. There are currently no policy initiatives envisaged with regard to nutritional claims.

2. Health Claims

With regard to health claims, Belgian legislation does not use the same wording as Directive 79/112, which forbids making reference to the prevention, curing or treatment of diseases. Instead, the word 'illness' and any synonyms of it, certain health-related words, pictures and/or references are forbidden. It is clear that disease risk reduction claims, as defined under the latest Codex recommendations on health claims are not allowed under Belgian law.

Due to the elaboration of the voluntary code of conduct on health claims (see below), the Belgian authorities have indicated that there will be a need to revise the working of the legislation on food advertising, in order to allow disease risk reduction claims.

The Belgian food industry considers current legislation far too restrictive. In particular, the authorisation system for foodstuffs for particular nutritional uses and the pre-clearance system for foodstuffs to which nutrients have been added.

3. Ethical Claims

NGOs, such as Max Havelaar and Oxfam, as well as consumer associations have been the driving force behind social labelling. Public authorities and industry have also become more and more interested in the issue. There are currently two legislative proposals on the table. On the one hand, a draft law for the promotion of socially responsible production. In order to promote a socially responsible product, the draft law foresees a certificate for companies and a label for their products if they fulfil certain ILO standards. The exact modalities for obtaining both the certificate and the label are still to be determined in the form of a Royal Decree. Under the law, a Council of Appeal will be set up to handle complaints on the abuse or misuse of the label.

On the other hand, a draft law is proposed on adding labelling and advertising provisions with an ethical notion to the Belgian law on unfair competition and consumer information. The amendment foresees that ethical claims may be considered as misleading advertising and proposes to establish fines for companies, which make ethical claims in their advertising without substantiating them.

C. VOLUNTARY CODES OF PRACTICE

1. Nutritional and Health Claims

While no voluntary codes on nutritional claims are planned, the food industry has been the driving force for the elaboration of a voluntary code on health claims. It has been elaborated together with manufacturers, distributors, scientists, consumer associations and the government. The distributors and the Health Council have so far approved it, but consumers are still hesitant and do not see it as a priority. The code distinguishes between four types of health claims (nutrient function claims, health effect claims, healthy eating patterns claims and disease risk reduction claims). It establishes a number of criteria for substantiating health claims and rules for using them on packaging or in advertising.

Its final adoption is planned for the end of 1999/beginning of 2000 and will – if all goes well – be starting a two-year test period thereafter.

The food industry is in favour of extending such a voluntary code to the whole of the EU. In order to achieve this it considers it necessary to have mutual recognition between the competent national authorities, and to move away from the idea that different national systems are necessary because the issue affects "public health".

2. Ethical Claims

There is a voluntary 'fair trade label' in Belgium, which is issued by the Max Havelaar group for coffee and bananas. The labels do not carry any claims, only the logo of the organisation.

D. VERIFICATION SYSTEMS

Under Belgian legislation, for foodstuffs for particular nutritional uses, as well as for nutrients and foodstuffs to which nutrients have been added, the proposed label and information on the composition of the product must be sent to the Ministry of Health.

For foodstuffs for particular nutritional uses, an authorisation has to be obtained from the Food Inspection Unit of the Ministry of Health prior to its marketing. A somewhat different pre-clearance system is in place for nutrients and foodstuffs to which nutrients have been added. A prior notification procedure applies for these products, whereby the Food Inspection can make comments within one month, notably asking the manufacturer to modify the labelling.

Post-clearance is undertaken by the Food Inspection Unit. The Food Inspection Unit receives annually approximately 500 notifications for nutrients and foodstuffs to which nutrients are added and conducts about ten a posteriori investigations per year.

The burden of proof is always with the third party that tables a complaint against a manufacturer. All third parties can take legal action. The fines imposed by the Food Inspection usually range between 250 and 1,250 Euro. According to the authorities and the food industry, there exists no case law on nutritional, health or ethical claims.

E. MEANS OF COMMUNICATION

There exist no differences between means of communication, except for the Belgian nutritional labelling decree, which does not apply to audio-visual means of communication.

F. CONSUMER PROTECTION

In general, the consumer association (Centre de Recherche et d'Information des Organisations de Consommateurs) pointed to the difficult of interpretation of health claims and that these were often misleading, as most people do not have a profound understanding of foodstuffs and the effect of particular ingredients. In order to increase the awareness of consumers and to bridge the knowledge gap, they have issued several publications on understanding nutrition and health claims.

G. TRADE BARRIERS

Overall, no problems were reported with regard to nutritional claims. The Belgian food industry indicated that there was sometimes a problem as a claim on a certain nutrient was allowed in one Member State but not in another.

Food industry considered Belgian legislation too restrictive, in particular the authorisation system for foodstuffs for particular nutritional uses and the pre-clearance system for foodstuffs to which nutrients have been added. The Belgian food industry pointed out that there are trade barriers between all EU Member States, but they are not always visible mainly because of the different languages used. They were, however, visible between countries that use the same language (e.g. Belgium-The Netherlands). The food industry refers to these barriers as "language induced trade barriers".

There have been no problems reported with regard to ethical claims.

H. CASE LAW

According to the Food Inspection Unit, there is no known case law on nutrition, health or ethical claims. The Belgian Food Industry Association (FEVIA) conducted research a short while ago and did not find any records of case law.

I. STAKEHOLDER ANALYSIS

Belgium has introduced a system, which allows for the verification of many claims. As for foodstuffs for particular nutritional uses, an authorisation system applies. For nutrients and foodstuffs to which nutrients have been added, a pre-notification system

applies. Belgium is also one of the very few countries where ethical claims have been very much on top of the agenda and in which legislation is being prepared in this area.

1. Government Authorities

- On nutritional claims, no need for review is seen.

- On health claims, authorities acknowledge that legislation has to be modified in one form or the other, in order to allow disease risk reduction claims, following the adoption of the Belgium voluntary code on health claims.

2. Consumers

- Consumers underlined that health claims are often misleading, as most consumers do not have a deep knowledge about foodstuffs and the effect of particular ingredients.

3. Industry

- On health claims, industry considers the voluntary code currently being elaborated in Belgium a step in the right direction. Industry is in favour of extending such a code to the whole of the EU.

- On ethical claims, the overall opinion seems to be that these are useful to promote products that have been ethically manufactured. However, a clear regulatory framework should apply for such claims.

* * *

II. MEMBER STATE POLICY

A. DEFINITIONS OF CLAIMS

1. Nutritional Claims

The definition of nutritional claims in Belgium is given in the Royal Decree on nutritional labelling of foodstuffs of 8 January 1992 (published in the Belgisch Staatsblad/Moniteur Belge of 21 February 1992, see annex I). Art.1, §2 states that:

Nutritional claims are considered to be all indications, representations and advertising messages which state, suggest or imply that a foodstuff has particular nutritional characteristics or qualities with regard to energy content, i.e. it:
- *supplies,*
- *supplies to a higher or lower level, or*
- *does not supply,*

and/or with regards to nutritional substances/content, i.e. it:
- *contains,*
- *contains to a higher or lower level, or*
- *does not contain.*

Furthermore, the qualitative or quantitative indication of a nutritional substance does not constitute a nutritional claim as these are described by the decree and the Minister responsible may decide in certain cases whether the conditions foreseen in this section are being met.

The definition is a literal translation from the EU Directive on Nutrition Labelling.

Art. 11 of the law on nutritional labelling also amends Art.3, §3 of the royal decree on advertising of foodstuffs of 17 April 1980 (published in the Belgisch Staatsblad/Moniteur Belge of 6 May 1980, amended by the royal decree of 4 August 1983, see annex II). It now states that nutritional claims used in advertising of foodstuffs must contain the same information given on the label of the product as defined by the law on nutritional labelling. This does, however, not apply to advertising via audio-visual means.

2. Health Claims

There is no direct definition of what a "health claim" is in Belgium. There are, however, restrictions with regards to the use of health-related words, pictures and/or references on labels and in advertising. These are defined by the Royal Decree of 17 April 1980 on Advertising of Foodstuffs (article 2 and 3). They state that the following is forbidden:

- the use of the words "hygiene", "medical", "ill" or "illness" and any variations, translations or synonyms of these words;
- the name of illnesses, depicting symptoms of illnesses and depicting people suffering from an illness;
- references to reducing weight/thinning down;

- the names or pictures of organs, blood, the circulatory and nervous system and the effect the foodstuff could have on them;
- pictures of people, clothes or equipment which make reference to the medical, paramedical or pharmaceutical profession;
- references to recommendations, certificates, declarations or medical opinions as well as endorsements, except of the statement that a foodstuff may not be taken in against a medical opinion;
- references to the Minister, the Ministry of Public Health or the services, civil servants or regulations of the Ministry of Public Health or any other bodies active in the area of public health;
- the use of the words "biological", "organic", "reform" and any variations, translations or synonyms of these words;
- the use of the words "natural", "pure" and any variations, translations or synonyms of these words; and
- the use of the words "nutritious", "high-energy", "low-calorie", "high-calorie" and any variations, translations or synonyms of these words.

Advertising as defined in this royal decree also includes labelling.

It is interesting to note that the Belgium decree is not using the wording used in Directive 79/112 that reference to the prevention, curing or treatment of diseases are not allowed. Nevertheless, as the word 'illness' and any synonyms of it are forbidden, it is clear that disease risk reduction claims, as defined under the latest Codex recommendations on health claims are not allowed under Belgian law.

3. Ethical Claims

There is no definition of ethical claims in Belgian legislation yet, but legislation has been proposed and the proposed modification of the law on unfair competition (see section B.2.b) includes the following wording on ethical claims in §1:

"…ethical claims of a philanthropic or humanitarian nature or claims which evoke the generosity of consumers".

B. LEGISLATION IN PLACE

1. Nutritional Claims

The EU Directive on Nutritional Labelling for Foodstuffs of 24 September 1990 was transposed into Belgian Law by the Royal Decree on Nutritional Labelling of Foodstuffs of 8 January 1992 and the Royal Decree on the Marketing of Nutrients and Foodstuffs to which Nutrients have been added of 3 March 1992 (Moniteur Belge/Belgisch Staatsblad, 15 April 1992, see annex III).

The EU Directive on PARNUTS 89/395/EEC of 3 May 1989 was transposed into Belgian legislation by the Royal Decree of 18 February 1991 relating to Foodstuffs for Particular Nutritional Uses (Moniteur Belge/Belgisch Staatsblad, 30 August 1991, annex XI).

2. Health Claims

Health claims are mainly regulated by the Royal Decree of 17 April 1980 on Advertising of Foodstuffs. This decree regulates the use of health claims and defines what types of claims may be used and what types of restrictions apply.

The relevant provisions of the EU Directive on Misleading Advertising have been transposed into Belgian law by the Law on Unfair Competition of 14 November 1983, modifying the law of 14 July 1971 (Moniteur Belge/Belgisch Staatsblad, 8 December 1983, see annex IV) and the Law on Unfair Competition and Consumer Information and Protection of 14 July 1991 (Moniteur Belge/Belgisch Staatsblad 29 August 1991, see annex XII).

3. Ethical Claims

Not applicable.

C. EXISTING PROHIBITIONS, RESTRICTIONS AND EXEMPTIONS

1. Nutritional Claims

Nutritional claims that may be used are restricted to the ingredients referred to in the relevant legislation. We have not come across any particular ingredients that have been described as particularly problematic or that have been left out.

2. Health Claims

For the restrictions on health claims, see chapter II. A. 2.

3. Ethical Claims

Not applicable.

D POLICY DEVELOPMENTS AND STAKEHOLDERS' POSITIONS

1. Health and Nutritional Claims

There are no new legislative initiatives on nutritional claims or health claims. The government has, however, indicated that there will be a need to revise the working of the legislation on advertising of food with regard to health claims once the code of conduct (see section III. A). 1.) has been approved.

According to the food industry, the voluntary code of conduct (see section III. A. 1.) that is currently being drawn up is a step in the right direction and will allow for a system in which industry takes responsibility. There is a necessity to extend such a code to the whole EU on the basis of the nutritional labelling directive. In order to achieve this, it will be necessary to have mutual recognition between the competent national authorities and to move away from the idea that different national systems are necessary because the issue affects "public health".

The main criticism of industry is that Belgian legislation is too restrictive (more restrictive than in other EU Member States). In particular, the authorisation system for foodstuffs for particular nutritional uses and the pre-clearance system for foodstuffs to which nutrients have been added is considered cumbersome (see chapter V).

In Belgium, the use of the word "disease" is prohibited. In The Netherlands, its use is possible. Industry indicated that manufacturers have adapted themselves and the claim does, therefore, not figure on the label. The same applies for claims on certain nutrients. Sometimes they are allowed in one country but forbidden in another. In order not to have to produce different packaging, manufacturers need to go for the minimum instead of the most applicable claims.

The Belgian food industry pointed out that there are trade barriers between all EU Member States, but they are not always visible mainly because of the different languages used. They are, however, visible between countries that use the same language as, for example, Belgium and The Netherlands (or Austria and Germany, see report on Austria). The Belgian food industry refers to these barriers as "language induced trade barriers".

The centre de Recherche et d'Information des Organisations de Consommateurs (CRIOC/OIVO) was particularly helpful. In general, CRIOC/OIVO have pointed to the difficulty of interpretation of health claims and to the fact that they are very often misleading as most people do not have a profound understanding of foodstuffs and the effect of particular ingredients. In order to increase the awareness of consumers and to bridge the knowledge gap they have issued several publications on understanding nutrition and health claims (see CRIOC/OVIO publication in annex X).

2. **Ethical Claims**

Industry indicated that they believe ethical and social claims to be an interesting and new field that is rapidly developing, in which consumer associations and NGOs have so far taken the lead.

No mention was made of the lack of consumer protection or barriers to trade.

Consumer associations are particularly interested in ethical and social claims as it has been a relatively unexplored area thus far. Social and ethical claims were also the subject of a conference on responsible consumption in December 1998 (see conclusions and recommendations attached, annex IX). Consumer associations declared that their aim is to establish a clear regulatory framework for social labelling. Social labels should inform consumers about the way in which goods are being produced and should make them confident that products with such labels have been produced under fair and socially responsible circumstances.

According to consumer associations, NGOs have been the driving force behind social labelling, e.g. Max Havelaar, Oxfam, etc., and a regulatory framework needs to take account of their experiences. From the consumer's point of view, social labelling is a necessity and should go in parallel with adequate and independent control.

Furthermore, social and ecological labels should be combined – while taking account of the different criteria used – as there is some competition among them already today. Combining them should be done in the interest of clarity and transparency vis-à-vis the consumer. No further explanations were given as to how this could be done.

Public authorities have also actively started to undertake measures to create a framework for social labelling. Like industry, they are interested in the topic and see it as one of the emerging issues on labelling. Several initiatives have been launched and both the Ministry of Economic Affairs and the Department of Development Co-operation are taking the lead. In addition, many members of parliament have a keen interest in the topic.

There are two legislative proposals aimed at creating a legislative framework for the use of social claims in Belgium.

a. Draft law for the promotion of socially responsible production

The idea behind socially responsible production was first spelled out by Ms Lisette Croes MP in a *proposition de loi* (law drafted by a Member of Parliament) on 10 November 1998. Both the government's own *projet de loi* on the same issue and Ms Croes' *proposition de loi* were discussed and adopted by the Belgian Chamber of Representatives on 28 April 1999 and transferred to the Belgian Senate (see annex V) on that day. The procedure was definitively cancelled, however, due to the fact that national elections were held six weeks later.

The draft law aims in the first place at promoting socially responsible production by looking at the production process. To achieve this goal, the draft law foresees a certificate for companies and a label for their products. The criteria for obtaining such a certificate and social label are the implementation of the five basic criteria of the International Labour Organisation (ILO):

- prohibition of forced labour (no. 29 & 105);
- right to form trade unions (no. 87);
- right of gathering and collective bargaining (no. 98);
- prohibition of discrimination in terms of employment and salary (no. 100 & 111); and
- minimum age for child labour (no. 138).

The certificate and label is voluntary and is granted for a period no longer than three years to companies (including their subcontractors and suppliers), which fulfil the criteria as set out in the draft law. The exact modalities and procedure for obtaining both the certificate and the label are to be determined in the form of a Royal Decree, which will be prepared by the Council of Ministers. The control will be assumed by institutions accredited according to the law of 20 July 1990 on the accreditation of certificates and control-organisations, as well as laboratories.

If the label is used counter to the provisions of the law, the permission to use it will be withdrawn (Art 11, §1). In case of abuse of the law (in particular use of the label without approval and misleading advertising) fines can be imposed from eight days to five years imprisonment and/or €120 to €120,000 (Art 12). A Council of Appeal is,

furthermore, to be set up within the Ministry of Economic Affairs to handle complaints by (all) third parties about the abuse or misuse of the label as well as appeals regarding the refusal or withdrawal of the label.

The draft law also establishes a Committee on Socially Responsible Production, which will issue opinions on all laws, amendments and decrees on the implementation of this draft law.

The government has the right to take up the thread and take new initiatives.

b. Addition of labelling and advertising provisions with an ethical notion to the law on unfair competition and the information of the consumer of 14 July 1991

This amendment of the law on unfair competition of 14 July 1991 (see annex VI) goes hand in hand with the proposal by Ms Croes. The amendment foresees that ethical claims may be considered as misleading advertising and proposes to establish fines for companies, which make ethical claims in their advertising without substantiating them. The aim is to encourage companies to provide the consumer with information about their production methods by giving them a comparative advantage in their advertising.

The amendments propose to enlarge the competencies of the Committee on Green Advertising (which is a subgroup of the Consumer Council, which itself is attached to the Economic Ministry) to include social/ethical criteria and to take legal action against companies misusing such claims. The proposal includes the participation of NGOs in the Committee and gives them the possibility to start legal action.

III. VOLUNTARY INSTRUMENTS

A. VOLUNTARY INSTRUMENTS IN PLACE

1. Nutrition and Health Claims

On the basis of an opinion from the Belgian Health Council of 1996 (see annex VIII) discussions about nutrition and health claims were started in Belgium.

In its opinion, the Health Council proposed the establishment of a positive list of claims that may be used on the basis of generally accessible scientific knowledge. For claims on the positive list, verification would be *a posteriori* and for claims that are cleared on the basis of a dossier it would be *a priori*. The list would be established by a multi-disciplinary committee of experts appointed by the Minister responsible for public health. The Food Inspection Unit of the Ministry of Social Affairs, Health and Environment would have a final say on how to deal with infractions. The Health Council also proposed the establishment of a short list of claims that could not be accepted at any time, as they would not be able to have scientific backing.

Industry reacted negatively to the proposals put forward by this opinion saying that a list prevents industry from assuming its own responsibility and that a voluntary code

would be much more useful and effective. Industry was particularly opposed to a list, which in its opinion has many disadvantages. Consequently, a voluntary code for health claims has, since then, been drawn up between government, manufacturers, distributors, scientists and consumer associations (see draft of January 1999, annex VII). The distributors and the Health Council have approved it, but consumers are still hesitant and do not see it as a priority.

The code has not been discussed for some time due to the dioxin crisis. However, it is expected to be fully finalised by the end of this year, or the beginning of next year. If all goes well, it will be starting a two-year test period at that moment.

The code is not fully compatible with the Royal Decree on Food Advertising (Annex II) because legislation forbids all health claims; and when the code will enter into force a *modus vivendi* will have to be established for them to exist in parallel. The government has stated that it is prepared to make and/or endorse the necessary adaptations.

2. Ethical Claims

There is a so-called (voluntary) 'fair trade label' in Belgium issued by the Max Havelaar group for coffee and bananas. Max Havelaar works together with manufacturers/producers via the FLO (international fair trade labelling organisation). Labels only apply to food products not textiles. The labels do not carry any claims, just the logo of the organisation.

The Max Havelaar label stands for ethical business practice, in the sense that the company in question does give farmers in third world countries the possibility to earn a fair amount of money.

The Max Havelaar group does not have any active support from the Belgian government but does co-operate with the Department for development co-operation which set up the "Internationaal Huis/Maison internationale" (international house).

B. DEFINITIONS USED IN THE VOLUNTARY INSTRUMENTS

1. Nutritional Claims

Not applicable.

2. Health Claims

The voluntary code distinguishes between four types of health claims: "Nutrient Function Claims", "Health Effect Claims", "Healthy Eating Pattern Claims" and "Disease Reduction Claims" (see annex VII, pp. 4-5).

"Nutrient Function Claims" describe the role of a nutrient on the normal physiological functions of the body. They are based on generally accepted scientific knowledge.
E.g.:

- *"Calcium is necessary for a solid bone structure";* and
- *"Vitamin B2 is necessary for the metabolism of proteins".*

"Health Effect Claims" refer to a positive scientific effect of a foodstuff on someone's health. They are also applicable to non-nutritional substances, which offer positive health effects.
E.g.:

- *"A good intake of calcium reinforces the bones";* and
- *"Product X reduces the cholesterol level"*

"Healthy Eating Pattern Claims" refer to official recommendations by national or international organisations about healthy eating patterns, nutritional recommendations or similar recommendations.
E.g.:

- *"The National Nutrition Council recommends a daily intake of 800mg of calcium. The product X contains 120mg/dl of calcium."*

"Disease Reduction Claims" refer to the effect the consumption of a particular foodstuff can have on reducing the risk of getting a certain disease. The claim may, however, not refer to the prevention of a disease but merely indicate the benefits of healthy eating habits as a guarantee for a better health.
E.g.:

- *"An adequate intake of calcium may help to reduce the risk of osteoporosis";* and
- *"Product X can contribute to reducing the risk of cardiovascular diseases"*

The code indicates that a number of criteria apply in the communication of these claims:

- Health claims have to be clear and cannot be misleading.
- Health claims have to be as precise as possible with regard to the description of the effect.
- Health claims cannot imply any extrapolation or generalisation of the proven scientific findings.
- Health claims have to be complete (i.e. indication of nature, form, dosage etc.).
- A claim has to be considered in the framework of a normal diet.
- Health claims shall not incite the adoption unbalanced eating habits or overconsumption of foodstuffs.
- The advantages shall not be presented in an exaggerated manner.
- Health claims, which propose or suggest a solution for problems, which do not exist in the national context, are forbidden.
- Health claims shall not suggest that normal health is affected if the foodstuff in question is not used.
- Health claims shall not imply or suggest that the use of the foodstuff in question guarantees normal health.
- Health claims shall not use detailed descriptions or representations of organs or physiological functions, which could lead persons to make wrong judgements about their own status of health.

3. Ethical Claims

Not applicable.

C. VOLUNTARY INSTRUMENTS ACCEPTED/RECOGNISED BY THE AUTHORITIES

1. Nutritional Claims

Not applicable.

2. Health Claims

The voluntary code will be recognised by the authorities as soon as it has formally been approved by them.

The voluntary code is not yet in force. It is, therefore, too early to comment on barriers to trade or consumer protection. Nevertheless, consumer associations seem to be rather hesitant about this voluntary code.

3. Ethical Claims

Not applicable.

IV. VERIFICATION SYSTEMS

A. CRITERIA FOR SUBSTANTIATING CLAIMS

1. Health and Nutritional Claims

Concerning foodstuffs destined for particular nutritional uses, as well as for nutrients and foodstuffs to which nutrients have been added, the proposed label and information on the composition of the product must be sent to the Ministry of Health (see below point B).

There is no format or guidelines to be observed in the dossier but the better the scientific information and backup provided the easier it is for a case to be accepted by the authorities.

The voluntary code on health claims provides for a number of criteria for substantiating health claims:

- The company responsible for placing a product on the market has to be able to proof the claim scientifically.
- The scientific dossier has to refer to the whole foodstuffs and not only to the substance with the health effect

Regarding this evidence, the code indicates that it could be expected to come from:

- scientific literature
- in vitro studies
- animal models
- clinical studies
- epidemiological studies
- any other relevant studies

A distinction is, nevertheless, being made between 'generic claims' and 'new' claims. For generic claims bibliographic evidence may be considered to be sufficient. For new claims the scientific evidence required has to be "complete and significant".

For generic claims and new claims:

- The studies used have to have been supported by objective scientific tests (e.g. peer reviewed, consensus position, judgement of independent experts etc.).
- The studies used have to be undertaken with a representative and pertinent segment of the population.
- The studies used have to be based on the consumption of foodstuffs in a reasonable quantity and frequency, i.e. a normal food consumption.
- The studies used have to have been carried out over a sufficiently long period.
- The studies must be quantitatively and statistically pertinent.
- The measured result of the study must be sufficiently important, in order to proof the health claim.

2. Ethical Claims

There is no verification system for ethical claims at present but proposed legislation may include a verification system for a company's production practices but it is unclear what form of verification will be proposed.

B. LEGAL/ADMINISTRATIVE SYSTEMS FOR VERIFYING CLAIMS

1. Pre-Clearance Rules/ Guidelines

Before marketing a foodstuff for particular nutritional use, a manufacturer has to obtain an authorisation from the competent national authority, i.e. the Food Inspection of the Ministry of Health (see § 7 of Royal Decree on Foodstuffs for Particular Nutritional Uses, see Annex XI). To this end the proposed label and information on composition of the product must be sent in. The authorities can ask for further information, if they consider it necessary.

The Supreme Health Council, which consists of about 100 scientists, doctors, professors etc. has to give an opinion on the application for marketing. The Supreme Health Council also examines the claim made. The Ministry of Health takes the final decision.

The Supreme Health Council has to give an opinion within four months, but the Ministry can extend this period to 8 months, if requested by the Supreme Health

Council. Furthermore, where the authorities ask for additional information from the manufacturer, the deadline is further extended.

For nutrients and foodstuffs to which nutrients (i.e. vitamins, minerals, amino acids) have been added, an a priori notification procedure applies (see Royal Decree on Marketing of Nutrients, see Annex III).

A dossier has to be sent to the Food Inspection Unit. A dossier has to be submitted indicating the nature of the product, the ingredient list, a nutritional analysis, the labelling and the necessary documentation enabling the Food Inspection to evaluate the nutritional value of the product. Within one month, the Food Inspection Unit can make comments, notably asking the manufacturer to modify the labelling. Furthermore, it can ask for further information on the bio-disposability of the nutrients.

The manufacturer is then given a number, which needs to be placed on the label of the product. The number indicates that the product has been cleared by the administration.

Industry indicated that the pre-clearance system for claims is cumbersome. The system (application and verification) is, however, rather weak (mainly because of under-staffing) and many exceptions are being made. The system is, therefore, not at all transparent.

The Food Inspection believes that the current a priori clearance system for nutrients and foods to which nutrients have been added is quite performing – 500 applications a year, 5,000 since 1980. However, the intensity of ex post controls depends on the financial means at its disposal. It goes without saying that Food Inspection concentrates on the most 'serious' cases, the worst breaches of the law. The Food Inspection Unit investigates about 10 cases a year.

2. Post-Clearance Rules/ Guidelines

The Food Inspection Unit is responsible for verifying claims. Once products are on the market which bear claims that have not been cleared (see above) or could be considered to be misleading, the Food Inspection Unit can ask the company in question to take the product off the market (procedure verbale). It can also decide to take legal action against the company in question on the basis of the Law on Unfair Competition of 14 November 1983 (modifying the law of 14 July 1971, Moniteur Belge/Belgisch Staatsblad, 8 December 1983, see annex IV).

Also other manufacturers and social partners (including consumers) may draw to the attention of the Food Inspection Unit in a formal or informal way a possible infraction, or take legal action themselves (see below).

C. LEGAL PERSONS ENTITLED TO TAKE LEGAL ACTION

All third parties can take legal action and table a complaint with the Court of Commerce. If it agrees with the complaint, the Court may ask a manufacturer to stop selling and marketing the product in question. According to the gravity of the case, the Court may impose a fine.

In most cases, it is Food Inspection that transfers a case to the legal services of the Health Ministry, which is allowed to impose an administrative fine. If that fine is not being paid – which rarely occurs – the case is referred to the Court of Justice.

D. BURDEN OF PROOF

The burden of proof is always with the third party that tables a complaint against the manufacturer.

E. APPLICABLE PENALTIES

The Food Inspection Unit's usual fine ranges from 10,000 to 50,000 BEF (Euro 250 to Euro 1,250). A judicial fine is usually much higher and varies according to the gravity, scope and scale of the case.

V. CASE LAW

According to the Food Inspection Unit, there is no known case law on nutrition, health or ethical claims. The Belgian Food Industry Association (FEVIA) conducted research a short while ago and did not find any records of case law.

VI. MEANS OF COMMUNICATION

Legislation as well as voluntary agreements on health claims do not make any distinction between types of media (print, radio and television). Labelling and advertising regulations apply for all types of communication except for nutritional labelling, where legislation excludes advertising via audio-visual means (see section II. A) 1).

It is unclear what the status of the Internet is, i.e. who regulates the use of claims via websites. This will pose difficulties as products can be bought or advertised via the Internet, including products with claims or advertising containing claims not allowed in Belgium.

VII. STATISTICS ON CLAIMS

We could not find any statistics on claims in Belgium. We have, however, been informed by the Food Inspection Unit that it deals with approximately 500 notifications for nutrients and foodstuffs to which nutrients are added and conducts about ten a posteriori investigations every year. Until now a total of some 5,000 notifications have been made.

VIII. ANNEXES

I. Royal Decree on Nutritional Labelling of Foodstuffs (8 January 1992)
II. Royal Decree on Advertising of Foodstuffs (17 April 1980)
III. Royal Decree on the Marketing of Nutrients and Foodstuffs to which Nutrients have been added (3 March 1992)
IV. Law on Unfair Competition (14 November 1983 - modifying the law of 14 July 1971)
V. Draft Law for the Promotion of Socially Responsible Production (28 April 1999)
VI. Proposal to add labelling and advertising provisions with an ethical notion to the law on unfair competition and the information of the consumer of 14 July 1991
VII. Draft Voluntary Agreement on Health Claims (January 1999)
VIII. Opinion of the Belgian Health Council on Nutritional Claims (8 August 1996)
IX. Conclusions and Recommendations of the Forum on Responsible Consumption (CRIOC/OVIO, March 1999)
X. CIOC/OVIO Publication on Nutritional Labelling
XI. Royal Decree on Foodstuffs for Particular Nutritional Uses (18 February 1991)
XII. Law on Unfair Competition and Consumer Information and Protection (14 July 1991)

IX. DATABASE OF CONTACTS

D. DENMARK

I. EXECUTIVE ANALYSIS

A. INTRODUCTION

This study has, in general, been well received by all interested parties/stakeholders who together have been very co-operative in arranging to meet and provide information.

Whereas traditional nutritional claims are fairly well regulated and not subject to much controversy, more attention has been paid to health claims in the present discussion on a different and more liberalised practice for food related claims. The Danish authorities clearly recognises that the present regulatory situation for health claims is very restrictive and perhaps not in line with mainstream European/international policy developments. Ethical claims are a fairly new subject in Danish debate and have for the first time been discussed more thoroughly in a recent report published by the Consumer Agency.

B. MEMBER STATE POLICY

1. Nutritional Claims

The definition of a nutritional claim is the same as defined in EU law and, having adopted the nutrient content claim and comparative claim definition, is in accordance with the Codex guidelines. However, Codex's nutrient function claim has not been accepted. Government policy is directed towards consumer and health protection and ensuring the overall promotion of healthy eating habits. The Danish Food Directorate has prepared a note suggesting that Danish policy should be amended to accept nutrient function claims in accordance with Codex. However, there is no political commitment on this as yet.

2. Health Claims

The definition of health claims is, in essence, the same as that of the EU Directive, 79/112. However, in comparison to Codex they are more medicinal in their focus. As in the case above, consumer protection is at the heart of Danish policy and to date, they have taken a restrictive approach regarding the use of health claims. The fundamental view is that it is the composition of the overall diet rather than any single food product that is important to the health of consumers. Consequently, it is not relevant to consider using health claims, as they are likely to mislead the consumer. However, the Danish Government is also changing its policy thinking towards a potentially wider application of health claims (i.e., to accept generic as opposed to product related reduction of disease risk claims, along the lines of the US and Swedish model) and tends to favour the EU initiative.

3. Ethical Claims

No official definition exists for ethical claims, or any specific legislation, although the general clauses regarding correctness, honesty and non-misleading information in the Marketing Act would cover such claims. However, the Danish Government and the Consumer Agency are examining the issue and are effectively calling for a dynamic definition which, in their understanding would cover human rights, employees' rights, child labour, working environment, fair-trade, animal welfare and social engagement. They tend to favour the development of a new labelling system rather than trying to integrate the ethical dimension into other types of labelling. Furthermore, any new labelling initiative should not limit Third World countries to their current economic level. Rather it should improve it and not limit access to the Danish market, i.e. new ethical labelling initiatives must not act as a barrier to trade. An EU initiative was also favoured.

C. VOLUNTARY CODES OF PRACTICE

On nutritional claims, interestingly, the Nutritional Council, the Regional Food Control Authority of Copenhagen and a so-called "Healthy City-Project" have developed the S-label to indicate that products are lower in fat and in sugar. Some 15-20 companies and retailers have started to the use the S-label, which is in line with the existing legislation.

No voluntary codes or practices exist for health claims. By contract, ethical claims are being used more and more through such initiatives as the international Max Havelaar organisation, which has the elephant logo for tea and coffee products and there is also the Rugmark and Clean Clothes campaign. Voluntary systems for organic/ecological and quality labelling, recognised by the authorities, are also in place.

D. VERIFICATION SYSTEMS

As a framework, the Danish Marketing Practices Act provides an umbrella function covering all types of claims requiring that such activities are carried out in accordance with good marketing practice and makes it an offence to make use of any false or misleading information likely to affect the demand for goods and services. With regard to food products, it is the Food Directorate and the regional food control units which are responsible.

There is in essence no pre-clearance, although inquiries can be made to both organisations. The Food Directorate would not provide a legal opinion, as they are responsible for handling complaints and act as the final controlling authority. The only exemption is the pre-clearance system under the PARNUTS Directive. As to post clearance, it is the responsibility of the regional food control units to supervise the law and they can change the labelling or marketing, prohibit sales and impose fines. If there were no compliance, they would take the case up to the Food Directorate who could then take them to the civil court. Anyone can complain to the local or regional food control unit or to the Consumer Agency. The burden of proof lies with the legal person responsible for the claim.

E. MEANS OF COMMUNICATION

No differences exist in the applicability of the relevant legislation/guidelines regarding the means of communication used such as television, internet, press, labels, etc. concerning the interpretation seen from the authorities' point of view. There is, however, an interesting case concerning a product whose benefits were advertised in press material. An examination is now taking place to decide whether press materials are covered by the Food Act.

F. CASE LAW

No examples of relevant case law exist in this area. However, on a number of occasions the authorities have administratively issued orders to change existing marketing practices with reference to both misleading advertisement and the use of health claims.

G. CONSUMER PROTECTION

The question of consumer protection is regarded as very important in the Danish political context and this question is also central to the authorities when considering any new regulations or any changes in administrative practices. Consumer (protection) issues are regarded as being more important today than ever before.

H. BARRIERS TO TRADE

It is generally accepted that Danish laws and practices on nutritional claims do not act as a barrier to trade as the policy is the same for both Danish and non-Danish products. However, the Danish policy regarding health claims can in some cases be seen as a barrier to trade since a food product with a scientifically well documented health effect will not be permitted to use such a claim in the marketing of the product.

I. STAKEHOLDERS POSITIONS

1. Government and enforcement authorities

- On both nutritional and health claims, government policy is directed toward consumer and health protection. Overall they have been restrictive in their approach. Nevertheless, there is now a shift in policy to allow both nutrient function claims and possibly generic reduction of disease risk claims. On ethical claims, there is a call to define exactly what they are and to develop an appropriate labelling scheme.

2. Consumer Organisations

- The Danish Consumer Association is clearly in favour of legislation and government endorsement of claims in labelling and advertising. An independent body should control any claims and the association supports real sanctions. More specifically, the association has supported the restrictive Danish practice regarding health claims. The Consumer Association strictly opposes health claims of a specific food product.

3. Industry Representatives

- The food industry wants a liberalisation of current restrictive practice and would like to introduce health claims in the marketing of food products. Interestingly, the Danish industry would support a system involving government endorsement as industry believes that this will add to the credibility of claims.

In conclusion, Denmark would welcome new initiatives from the EU Commission regarding health claims.

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II. MEMBER STATE POLICY

A. DEFINITIONS OF CLAIMS

1. Nutritional Claims

Nutritional claims are defined in the Nutritional Declaration Act No. 198 of 20 March 1992. (Bekendtgørelsen om næringsdeklaration m.v.) Article 1, section 5 (1) contains the following definition:

> *"A nutritional claim means any presentation on packaging, in the presentation or in advertising, which is suited to give consumers the impression that a food product has particular nutritional properties due to energy or nutrients."*

The Danish definition of a nutritional claim is basically in accordance with the EU definition.

Furthermore, the Danish definition is in accordance with the Codex Alimentarius (herein referred as Codex) definition of nutritional claims. As will be described later on, the Danish Authorities have adopted the Codex "nutrient content claim" and the "comparative claim", whereas the Codex "nutrient function claim" is not accepted as a nutritional claim.

2. Health Claims

Health claims are defined in the Danish Food Act (Levnedsmiddelloven) No. 310 of June 6, 1973 with amendments: In Article 4, section 28 (2) it is stated:

"It is forbidden in advertisements, etc. or on packaging to cite:

- *information that may cause or exploit fear in the consumers, and*
- *Information that may cause doubt as to the propriety of using other similar food products."*

Section 28 (3), which is the most central one in relation to the question of definition, states:

"It is forbidden in advertisements, etc. or on packaging to cite:

- *that a food product is recommended by doctors, or that consumption of the food product may prevent, relieve or have a beneficial effect on diseases or symptoms of disease."*

Thus, the Danish definition is fairly similar to the EU definition in Article 2 of the 1979/112 Labelling Directive.

In the latest Codex definitions of health claims from April 1999 (still at discussion stage), two different definitions are used. It is interesting and important to note that neither of these definitions includes words like "preventing, treating or curing."

Consequently, a comparative analysis regarding the Danish and the EU definition vis-à-vis the Codex definitions suggests that these are not really in accordance with each other, i.e. the Danish and EU definitions are more "medicinal" than the Codex definitions.

3. Ethical Claims

No official definition exists for ethical claims. The subject of ethical labelling is, however, becoming an item on the agenda of the Danish Government/Consumer Agency. The Consumer Agency will publish a report (Labelling: The Labelling Committee's Review, The Consumer Agency, Ministry of Business and Industry) on labelling of consumer goods in July 1999. This report also looks into the area of ethical labelling.

As far as definition is concerned, the report refers to the definition used in the New Economics Foundation's report: Social Labels: Tools for Ethical Trade:

> *"Social labels are words and symbols associated with products or organisations which seek to influence the economic decisions of one set of stakeholders by describing the impact of a business process on another group of stakeholders."*

Further on, the Danish report emphasises the need for a "dynamic definition", as new ethical themes will surface over time. Presently, the Consumer Agency thinks that some of the relevant issues for potential ethical labelling would be: human rights, employee's rights, child labour, working environment, fair-trade, animal welfare and social engagement.

B. LEGISLATION IN PLACE

1. Nutritional Claims

Nutritional claims are regulated by

- *The Food Act, Article 4, section 23 regarding non-misleading of the consumer and Section 29 regarding nutritional value information.*
- *The Nutritional Declaration Act, Article 1, section 5 regarding definition and Article 3, section 11 regarding applicable nutrients.*

Furthermore, the Danish Veterinary- and Food Directorate, which will be renamed The Danish Food Directorate as of 1st August 1999, has issued guidelines relating to the Nutritional Declaration Act and specific guidelines for the use of "light" claims.

The Council Directive 90/496/EEC on nutritional labelling for food products is implemented in the Food Act and in The Nutritional Declaration Act.

2. Health Claims

Health claims for foods including dietary supplements are regulated by:

- *The Food Act, Article 4, section 23 regarding non-misleading of the consumer*
- *Section 28 (2) and (3) regarding prohibition and definition of health claims.*

The Danish Food Directorate has published guidelines regarding the administration of section 28 (2) and (3) of the Food Act.

The Council Directive 79/112 on Labelling of food products is implemented in the Food Act.

Health claims for natural remedies are regulated by The Medicinal Products Act.

3. Ethical Claims

There is no specific legislation in place regarding ethical claims. However, any claim - including ethical claims - is subject to the general clauses regarding correctness, honesty and non-misleading in The Marketing Act.

C. EXISTING PROHIBITIONS, RESTRICTIONS AND EXEMPTIONS

There is nothing special to report.

D. POLICY THINKING AND STAKEHOLDERS' POSITIONS

1. Nutritional Claims

The essence of policy thinking regarding claims is related to consumer protection, in particular, not misleading the consumer. In relation to food products, the policy thinking also includes consumer safety, consumer health and the overall promotion of healthy eating habits. With regard to nutritional claims, the Danish policy has in general been coherent with Codex guidelines and EU policies/directives.

The nutrient content claims and the comparative claims are administered in accordance with the Codex Guidelines on Nutrition Labelling and Nutrition Claims. The declaration of nutrient content is voluntary but if a nutritional claim is made, the food product must be labelled with a nutrient declaration in accordance with the EU Directive on nutrition labelling and the Codex Guidelines.

The adoption of the Codex Guidelines for Use of Nutritional Claims in 1997 includes nutrient function claims. From now on, the Danish Government regards these claims as health claims. Consequently, nutrient function claims have been forbidden according to the general prohibition regarding health claims in the Danish Food Act.

Concerning nutritional claims relating to "low", "free", "high" etc., the Danish policy is in line with Codex recommendations and criteria. With regard to the claim "light" the Danish Authorities have introduced rules somewhat stricter than the Codex Guidelines.

The Danish Food Directorate, which is part of the Ministry of Food, Agriculture and Fisheries, and which acts in matters relating to nutrition and health policies of the

Ministry, in a note to the Ministry, suggested in April 1999, that the Danish policy ought to be changed. It is generally recommended that the administrative practice is adapted to include the nutrient function claims according to the Codex guidelines adopted in 1997. Up until now, no firm political commitment has been made on this recommendation from the Food Directorate.

The Danish policy regarding nutritional claims can hardly be said to act as a barrier to trade. The policy is administered similarly towards both Danish and foreign companies. A restrictive policy regarding claims does not exclude an otherwise fully legal and acceptable food product from being marketed on the Danish market.

The question of consumer protection is regarded as being very important in the Danish political context and this question is also central to the authorities when considering any new regulations or any changes in administrative practices. Consumer (protection) issues are regarded as being more important today than ever before.

2. Health Claims

The overall policy thinking regarding health claims is similar to the policy mentioned under nutritional claims.

Furthermore, it is relevant to add that the Danish Authorities have traditionally taken a very restrictive attitude regarding the use of health claims. The fundamental view is that it is the composition of the overall diet rather than any single food product that is important to the health of consumers. Consequently, it is not relevant to consider using health claims, as they are likely to mislead the consumer.

The Danish policy thinking regarding health claims has been summarized in 1998 as follows:

> *"All types of claims related to diseases or symptoms of diseases are prohibited. Physiological claims like "calcium is important for the formation and maintenance of bones and teeth" are classified as health claims and are, thus, prohibited. The same applies to all references to cholesterol. Health claims to food products are prohibited, whether documented or not. The authorities´ interpretation of the Food Act and its provision is restrictive."*

However, as discussed below, policy thinking is currently changing towards a potentially wider application of health claims.

The Danish Government is in favour of an EU initiative regarding harmonised terminology and regulations for health claims.

The Food Directorate is also undertaking a discussion regarding health claims.

The following has been concluded:

- *Physiological claims (earlier Codex terminology) or enhanced function claims (latest Codex terminology), are not considered a suitable way to convey health messages to the consumers. It is argued that the consumers will misunderstand*

such claims and most probably perceive these claims as disease reduction claims. Physiological claims will therefore often be considered misleading.

- *Health claims relating to a specific food product and the total diet (in the latest Codex documents referred to as "Reduction of Disease Risk Claims") should be considered and further explored. The Food Directorate has some sympathy for both the US and Swedish models which are based on a two-step principle i.e. that any claim relating to a specific food product is placed in the context of the total diet.*

There has to be a political response from the Ministry and the Parliament regarding these proposed policy changes.

The Danish policy regarding health claims can in some cases be seen as a barrier to trade in as far as a food product with a scientifically well documented health effect will not be permitted to use such a claim in the marketing of the product

3. Ethical Claims

The policy thinking concerning ethical claims/labelling, according to the mentioned labelling report, favours the development of a new labelling system rather than trying to integrate the ethical dimension into other types of labelling. Furthermore, any new labelling initiative should not limit Third World countries to their current economic level. Rather it should improve this level. It should also not limit access to the Danish market, i.e. new ethical labelling initiatives must not act as a barrier to trade.

The same report also stresses the need for a clearly defined purpose/foundation for a new ethical label and the need for EU co-ordination is also mentioned.

From now on, according to the report, very little experience has been gained regarding ethical claims/labelling and a concrete proposal for political action has been suggested:

> *"To gain practical experience with ethical labelling it is recommended that opportunities are created for companies, organisations (including NGO's) and public authorities to jointly seek public financial support to carry out pilot experiments with ethical labelling in selected areas."*

Such experiments should be evaluated after a three-year period. It is necessary to underline that this recommendation has not yet entered into the political phase of approval.

III. VOLUNTARY INSTRUMENTS USED

A. VOLUNTARY INSTRUMENTS IN PLACE

1. Nutritional Claims

The following voluntary instrument is in operation:

The Nutritional Council, the Regional Food Control Authority of Copenhagen and a so-called "Healthy City – Project" has developed an "S-label" indicating that products labelled in this way has a lower fat content and, in some cases, a lower sugar content than other food products in the same category. In reality, this S-label becomes a nutritional claim and as such it is regulated by existing legislation. Consequently, the use of the S-label requires a complete nutritional declaration.

The Copenhagen Food Control Authority assists in developing the S-label system. Some 15-20 food companies and some of the major retail chains have started to use this label.

A private company, Dansk Varefakta Nævn (DVN) has issued guidelines concerning nutritional claims and the company advises producers and importers in this area. The DVN guidelines fully reflect the legislation and guidelines of the national authorities.

2. Health Claims

No voluntary instruments - e.g. a self-regulating code of conduct - are in place.

3. Ethical Claims

The international Max Havelaar organisation has been active in Denmark since 1994. The Max Havelaar elephant–logo is used on coffee and tea and the intention is to expand the use of the logo to other product categories such as cocoa, cane-sugar, orange juice concentrate, etc.

The Max Havelaar organisation operates a licensing system including a set of criteria to which participating companies must adhere. Although market share remains fairly limited, the use of the elephant logo - measured by the volume of products sold - has increased steadily since 1995. In general, consumer awareness is also limited.

Other ethically based labelling systems e.g. the Rugmark, Clean Clothes Campaign and others are not really used to any extent.

The National Authorities have voluntary systems in place for organic/ecological and quality labelling. Both of these labels contain ethical elements, i.e. animal welfare.

Max Havelaar co-operates internationally with Transfair International and the Fair Trade Foundation and the different logos used are all about "fair trade and sustainable development/trade". Since 1997, all Fair Trade labelling is co-ordinated by FLO, the International Fair Trade Labelling Organisation.

B. DEFINITIONS USED IN THE VOLUNTARY INSTRUMENTS

No remarks.

C. EXISTING PROHIBITIONS, RESTRICTIONS AND EXEMPTIONS

No remarks.

D. VOLUNTARY INSTRUMENTS ACCEPTED/RECOGNISED BY THE AUTHORITIES

The S-labelling system, the guidelines from DVN and the organic and quality labelling systems are all accepted/recognised by the authorities.

The authorities also accept the Max Havelaar licensing system and logo but limited attention has been paid to the matter.

IV. VERIFICATION SYSTEMS

A. CRITERIA FOR SUBSTANTIATING CLAIMS

1. Nutritional Claims

The criteria for using nutritional claims are based on the relevant legislation and guidelines mentioned under Section II C 1, reflecting the 90/496/EEC Directive and Codex.

As mentioned earlier, any claim appearing on labelling, etc. makes nutrition labelling compulsory. As far as the allowed nutritional claims are concerned, i.e. content and comparative claims, these are based on quantitative criteria thereby making it relatively easy to verify if such claims are justified.

2. Health Claims

As all health claims are prohibited the discussion of criteria for substantiation becomes irrelevant.

3. Ethical Claims

The Max Havelaar licensing system is based on a set of principles and criteria to which all actors in the food value chain will have to adhere in order to use the elephant logo in their marketing.

The main criteria for the use of the Max Havelaar label/logo are: direct purchase, surcharge, guaranteed minimum price, credit allowances, long-term relations and production criteria for plantations.

The so-called Register Committees organisationally associated with the International Fair Trade Labelling Organisation (FLO) monitor compliance with these criteria.

The national authorities are not involved in any verification of the Max Havelaar label.

B. LEGAL/ADMINISTRATIVE SYSTEMS FOR VERIFYING CLAIMS

The Danish Marketing Practices Act (Act No. 428 June 1, 1994) applies to private business activities and to similar activities undertaken by public bodies. Section 1

requires that such activities are carried out in accordance with good marketing practices and Section 2 makes it an offence to make use of any false or misleading information likely to affect the demand for goods or services. The Consumer Ombudsman and the National Consumer Agency under the Ministry of Business and Industry in general administer the Marketing Act. However, as far as food products are concerned the authority and competence has been passed on to the Food Directorate under the Ministry of Food, Agriculture and Fisheries following the lex specialis principle. Furthermore, the Food Act referred to under II A includes regulation similar to the Marketing Act.

1. Pre-Clearance Rules/ Guidelines

Companies can take their marketing activities, including claims, to the Food Directorate. In reality, however, such inquiries will be directed to the regional food control unit and they will give an opinion on the legality of the initiative. The Food Directorate does not give any explicit statements on the legality of a specific claim, as they are the ones, which not only handle complaints but also act as the final controlling authority.

Therefore, in essence, no system is in place for pre-clearance. As an exemption to this general system, the Danish Authorities practice a kind of pre-clearance model as far as Products for Particular Nutritional Uses ("PARNUTS") products are concerned cf. Article 9 of the EU 90/496 Directive.

2. Post-Clearance Rules/ Guidelines

As mentioned above, the regional food control units supervise that laws and regulations are observed. These units can order companies to undertake concrete actions; for example, changing the labelling and marketing or prohibiting sales and imposing a fine.

If actions taken by the regional control units are not accepted by the companies, they can lodge a complaint with the Food Directorate, which will then take the final decision at the administrative level. These decisions, if not accepted, can then be taken to the civil courts.

C. LEGAL PERSONS ENTITLED TO TAKE LEGAL ACTION

Any legal person, including consumers or competitors, can complain to the local/regional food control unit or the Consumer Agency as far as food marketing including claims is concerned.

D. BURDEN OF PROOF

The burden of proof always rests with the legal person responsible for the marketing of the product and no specific kind of proof is adduced.

E. APPLICABLE PENALTIES

The applicable penalties when violating claims regulations are usually of limited size, i.e. below EUR 3-5.000. However, fines are rarely used, as the authorities will endeavour to settle any breach of the regulations/guidelines through negotiation.

V. CASE LAW

No examples of relevant case law exist in this area. However, on a number of occasions the authorities have administratively issued orders to change existing marketing practices with reference to both misleading advertisements and the use of health claims.

Recently, the Danish Authorities rejected the marketing of the drink Red Bull on the Danish market. The rejection, however, was based on the Danish regulations regarding the addition of nutrients rather than on claims.

Also very recently, the authorities (a regional food control unit) have submitted a notification to the police regarding health claims made in press material in relation to the marketing of the Swedish product ProViva with reference to section 28 of the Food Act.

VI. MEANS OF COMMUNICATION

There are no differences in the applicability of the relevant legislation/guidelines regarding the means of communication used such as television, internet, press, labels, etc. concerning the interpretation seen from the authorities' point of view. The ProViva case is putting this interpretation to the test as mentioned under Section V on Case Law. This investigates whether press material is also included under section 28 of the Food Act.

VII. STATISTICS ON CLAIMS

No data is available.

VIII. ANNEXES

1) Nutritional Declaration Act No. 198 of March 20, 1992 (Bekendtgørelse om næringsdeklaration m.v. af færdigpakkede levnedsmidler)
2) Danish Food Act No. 310 of June 6, 1973 (Lov om levnedsmidler m.m.)
3) Guidelines for nutritional declaration of prepared foodstuffs, (Vejledning om næringsdeklaration af færdigpakkede levnedsmidler), September 1993
4) Guidelines for health claims, (Vejledning om sundhedsanprisninger), The Veterinary- and Food Directorate, June 1993
5) The Danish Marketing Practices Act, Act No. 428 of June 1st, 1994

IX. DATABASE OF CONTACTS

E. FINLAND

I. EXECUTIVE ANALYSIS

A. INTRODUCTION

This study on nutritional, health and ethical claims was well received by all interested parties/stakeholders and together have been very co-operative regarding meetings and information.

At the time of this study, the National Food Administration (NFA) is reviewing its guidelines from 1996 to industry regarding nutritional labelling and nutritional claims to reflect Codex and scientific developments. Given a recent proposal from the Finnish Food and Drinks Industry, the National Food Administration is also reconsidering its current practice regarding health claims. There are indications that Finland will adopt a more liberalized attitude. The process is ongoing and the final outcome remains to be determined. The authorities are concerned that they do not infringe current legislation including the EU labelling directive.

B. MEMBER STATE POLICY

Policy thinking in Finland on nutritional and health claims is based on consumer protection (not misleading the consumer), combined with consumer safety and the promotion of healthy eating habits.

1. Nutritional Claims

Nutritional claims are defined in Finnish law and are in complete accordance with EU legislation as well as the Codex guidelines.

2. Health Claims

Whilst not explicitly defined in legislation, the Food Act states that presenting health claims or medical information concerning foodstuffs or referring to such information is forbidden - effectively in line with EU Directive 79/112. However, Finnish rules do permit in certain conditions that nutritional education may be supported by explanations of the positive effects of foodstuffs on vital functions when there is a clear connection between these. Thus, claims regarding the effects of foodstuffs or other substances on vital functions do not always fall under the ban. This type of "vital function" claim has to relate to the positive effect of the active ingredient rather than the foodstuff itself.

Health claims, which are permitted in Finland, are similar to enhanced function claims as defined in the draft Codex documents on health claims. Policy makers in Finland tend to favour an EU based regulatory framework with a list of acceptable and prohibited health claims.

The NFA has taken a positive stance towards a proposal from the Finnish Food and Drink Industry Federation to introduce product specific physiological health claims. However it is not prepared to consider so-called disease reduction claims without changing the Food Act or the Council Directive 79/112/EEC.

3. Ethical Claims

There is no specific legislation and/or definition regarding ethical claims, although the Consumer Protection Act applies.

C. VOLUNTARY CODES OF PRACTICE

1. Ethical Claims

The Finnish Association for promoting Fair Trade (Reilun Kaupan Edistämisyhdistys Ry) was established in 1998 and is associated with the International Fair Trade Labelling Organisation (FLO). The organisation uses the "elephant" logo as its ethical trademark, which was used on the market for the first time in August 1999. The Finnish International Development Agency has agreed to give financial support to the organisation.

D. VERIFICATION SYSTEMS

No pre-clearance system exists for claims (apart from the PARNUTS), although the NFA publishes guidelines concerning the interpretation of the Food Act and other relevant legislation. In terms of post-clearance, it is the Consumer Agency/Consumer Ombudsman and the NFA, which are responsible, together with the municipal/regional authorities. Cases are virtually never taken to court. Instead they are settled out of court by issuing prohibitions or information orders, combined sometimes with fines. The burden of proof lies with the legal person responsible for the marketing of the product.

E. MEANS OF COMMUNICATIONS

No differences exist in the applicability of the relevant legislation/guidelines regarding the means of communication used.

F. CONSUMER PROTECTION

Consumer protection is at the forefront of Finnish policy when it comes to labelling. There is generally a good working relationship between authorities and consumer organisations.

G. BARRIERS TO TRADE

It is fair to say that this is not an issue.

H. CASE LAW

According to the NFA, there has not been any decisions or court cases on an inappropriate use of health claims in foodstuffs since 1995 (before 1995 the Consumer Ombudsman had the responsibility for the market control of claims). Since 1995, the NFA has passed comment on unsuitable claims in ten instances.

I. STAKEHOLDER ANALYSIS

1. Government Authorities

- Whilst the authorities acknowledge that they have no defined position on ethical claims, the Consumer Agency has indicated that this will become a priority in the year 2000.

- On nutritional and, in particular, health claims, the Finnish Government is clearly in favour of a more liberal regime, possibly accepting enhanced function claims and specific physiological claims, although they are still sceptical about allowing disease reduction claims. They are in favour of Codex developments and support a clear EU regulatory framework with a positive and negative list of claims.

2. Consumer Organisations

- The two Finnish consumer organisations are generally in favour of the cautious approach by the National Food Administration. They are concerned about the possible introduction of health claims for individual products as they consider these potentially misleading. Therefore, they have a preference for the Swedish system with health claims in two-steps.

- The consumer organisations are equally concerned about the lack of what they perceive as inadequate resources for the supervision and control of health claims.

- The major consumer organisation, The Finnish Consumers` Association, has taken a proactive role in raising the awareness of ethical issues regarding the consumption of normal consumer goods.

3. Industry

- There is no indication from industry that modifications are needed concerning nutritional claims. As to health claims, the Finnish Food and Drink Industry Federation has proposed the introduction of product specific claims, along the lines of the Swedish proposal. The federation has also proposed disease risk-reduction claims in line with the European Union.

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II. MEMBER STATE POLICY

A. DEFINITION OF CLAIMS

1. Nutritional Claims

Nutritional claims are defined in a Decision issued by the Ministry of Trade and Industry concerning the nutritional labelling of foodstuffs (1496/1993: Handels- och industriministeriets beslut om näringsvärdesdeklaration for livsmedel).

In §1, section 2 (2), it is cited:

> *"A nutritional claim is a claim made on packaging, in a brochure or any other information in relation to marketing which is meant to state, imply or suggest that a foodstuff has special nutritional properties."*

It is also stated that such claims may concern energy, protein, carbohydrates, fat, fibre, sodium or parts of these nutritional groups as well as certain vitamins and minerals. Any compulsory information on the quality or quantity of nutrients does not constitute a nutritional claim. Nutritional declaration is, in general, voluntary.

The Finnish definition of a nutritional claim is in complete accordance with the EU definition and with the Codex Alimentarius definition. The Codex "nutrient content claim", "comparative claim" and "nutrient function claim" are all accepted in Finland.

2. Health Claims

Health claims are not explicitly defined in the Finnish Food Act. However, according to §6 of the Food Act, presenting health claims or medical information concerning foodstuffs or referring to such information is forbidden.

In Control 11/97 Medicinal and Health claims in the marketing of foodstuffs (Tilsyn 11/1997 Handbok för tillsynen över påståenden som gäller medicinska egenskaper och hälsan) issued by the National Food Administration (NFA), it is said that this prohibition to a large degree is based on Directive 79/112/EEC, which prohibits marketing claims to the effect that foodstuffs prevent, treat or cure human diseases.

The ban in §6 of the Food Act concerns all marketing of all types of foods including dietary supplements.

The Finnish "definition" of health claims thus reflects the EU definition.

In the latest Codex definitions of health claims from April 1999, two different definitions are used. It is interesting and important to note that neither of these definitions includes words such as "preventing, treating or curing."

Consequently, a comparative analysis regarding the Finnish and the EU definition vis-à-vis the Codex definitions suggests that these are not really in accordance with each other, i.e. the Finnish and EU definitions are more "medicinal" than the Codex definitions.

3. Ethical Claims

No definition exists.

B. LEGISLATION IN PLACE

1. Nutritional Claims

The regulatory framework for nutritional claims includes:

- *The Food Act*
- *The Decision concerning the nutritional labelling of foodstuffs*
- *The Consumer Protection Act*

The Council Directive 90/496/EEC on nutritional labelling is implemented in the Decision concerning nutritional labelling of foodstuffs.

2. Health Claims

The regulatory framework for health claims regarding foodstuffs and dietary supplements consists of:

- *The Food Act*
- *The Ordinance concerning labelling of foodstuffs*
- *The Consumer Protection Act*

Health claims/medicinal claims regarding natural remedies is covered by the Medicinal Act.

The Council Directive 79/112 on the labelling of Foodstuffs is implemented in the Food Act and the Ordinance concerning labelling of foodstuffs.

3. Ethical Claims

There is no specific legislation in place regarding ethical claims. However, any claim - including ethical claims - is subject to the general clauses regarding correctness, honesty and non-misleading information in the Consumer Protection Act.

C. EXISTING PROHIBITIONS, RESTRICTIONS AND EXEMPTIONS

Nothing special to report.

D. POLICY THINKING AND STAKEHOLDERS' POSITIONS

1. Nutritional Claims

Policy thinking on claims is guided by an overarching desire to protect and not to mislead the consumer. In relation to food products, consideration is also given to consumer safety, consumer health and the overall promotion of healthy eating habits.

With regard to nutritional claims, the Finnish policy has in general been coherent with Codex guidelines and EU policies/directives.

All kinds of claims used either in labelling or marketing must be in accordance with the totality of relevant legislation: the main laws being the Food Act, The Consumer Protection Act and the Decision concerning the nutritional labelling of foodstuffs.

Nutritional claims are, in general, administered according to the Codex guidelines on Nutrition Labelling and Nutrition Claims.

The NFA has issued guidelines for the use of nutritional declarations and nutritional claims (Valvonta 5/96) and is currently working on updating these guidelines. A new set of guidelines is expected to be produced in the Autumn of 1999.

2. Health Claims

Policy thinking is, to a large extent, reflected in the above-mentioned Control 11/97. According to the manual, the Food Act particularly prohibits claims according to which a person can prevent, treat or cure a disease or its symptoms by eating a given foodstuff. When evaluating the effect of a particular marketing practice, attention should be paid to the impression which it, as a whole, tends to create in the consumer's mind.

A claim may fall under the ban in Section 6 even if marketing does not mention the name of a specific disease. General claims referring to symptoms, discomfort, pain etc. may fall under that ban even if a specific disease is not mentioned. The manual also states that the name of a foodstuff may not make reference to a disease or be designed to create an association with a disease in consumer's mind.

Examples of forbidden claims in the manual include claims that a foodstuff or any of its ingredients prevent osteoporosis, relieve indigestion/upset stomach, prevent cavities or relieve symptoms associated with the menopause. Appended to the manual is a list of claims, which are seen to conflict with §6 of the Food Act.

However, according to the manual, in certain conditions nutritional education may be supported by explaining the positive effects of foodstuffs on vital functions when there is a clear connection. Thus claims regarding the effects of foodstuffs or other substances on vital functions do not always fall under the ban in Section 6 of the Food Act.

This type of "vital function claim" describes the effect of nutrients, compounds or microbes on normal vital functions. The manual says that acceptable claims are those which refer to vital functions with which nutrients have a clear connection. The term nutrient refers to substances in foodstuffs, which provide energy for growth, support the maintenance and development of life and whose absence causes certain biochemical and physiological changes.

Permissible claims include those referring to vital functions with which foodstuffs have a clear connection. In presenting claims, attention should also be focused on the general principles, which are mentioned below.

Permissible claims, under certain conditions, include the following examples, which refer to strengthening of bones, digestion, fat balance and blood cholesterol:

- *calcium strengthens bones*
- *xylitol is good for teeth*
- *fibre promotes digestion*
- *soft fats help keep the blood cholesterol under control*
- *a low-salt diet has a positive effect on the control of blood pressure: product X is low in salt and contains x grams of salt.*

In using claims referring to vital functions, the positive effect should apply to the active ingredients rather than the foodstuff itself. In marketing, therefore, it is permissible to state that calcium strengthens bones but it is not permissible to state that product X strengthens bones.

According to the manual, in evaluating marketing claims and especially claims referring to vital functions, attention should also be paid to the following matters/principles:

- The decisive thing for human nutrition and welfare is **total diet** and not any single food. In presenting marketing claims, which refer to vital functions, the significance of total diet should therefore be emphasized.

- The portion of an active ingredient in a food should be such that the **effect** presented in marketing is accomplished by regularly using normal amounts of the food as part of a normal diet.

- Permissible claims must be provable. If a claim regards anything but a generally known effect on vital functions, it must be based on sufficient scientific **proof**.

Finnish permissible health claims are similar to those referred to as enhanced function claims in the latest Codex documents on health claims. The current Finnish policy thinking is clearly in favour of an EU based regulatory framework for health claims. This has been stated in the Finnish comments in the Green Book on EU food policy/legislation. More precisely, Finland is in favour of explicit lists of acceptable and prohibited health claims.

The NFA has received a proposal from the Finnish Food and Drink Industry Federation regarding the possibility of introducing product specific physiological health claims (similar to the proposal made in Sweden) and so-called disease reduction claims.

After meeting with the NFA, we have personally been informed that the authorities will take a positive attitude towards physiological health claims, i.e. the NFA will require that a positive list be worked out between the authorities and nutrition experts. These approved claims will then eventually be integrated into the mentioned Control 11/97 guidelines.

In regard to the proposed disease reduction claims, the NFA has come to the conclusion that at present this is not possible without changing the Food Act or the Council Directive 79/112/EEC.

3. Ethical Claims

The Finnish Government has not really considered/addressed the issue of ethical claims. In a personal communication, the Consumer Agency has said that this issue will be one of three major consumer related subjects to be looked at in the year 2000.

III. VOLUNTARY INSTRUMENTS

A. VOLUNTARY INSTRUMENTS IN PLACE

1. Nutritional Claims

No additional comments.

2. Health Claims

No additional comments.

3. Ethical Claims

The Finnish Association for promoting Fair Trade (Reilun Kaupan Edistämisyhdistys Ry) was established in 1998 and is associated with the International Fair Trade Labelling Organisation (FLO). The organisation uses the "elephant" logo as its ethical trademark.

As with all member organisations of the FLO, the Reilun Kaupan Edistämisyhdistys Ry organisation has identical principles and criteria for its work and licensing schemes, i.e. for small farmers: democratic forms of organisation, no discrimination, political independence, good product quality, and for employee; fair salaries, the right to organize itself, no child labour, etc.

The first products with the elephant logo will appear on the market in August 1999. Four companies have signed licensing contracts with the Finnish Fair Trade organisation and some of the major retail chains have agreed to stock the products - initially coffee and tea.

The Finnish Association for promoting Fair Trade has been founded by various NGO organisations, including the trade unions for food and textile products. Initially, the Finnish International Development Agency has agreed to support the organisation with a total of approximately 640 000 EUR for its first three years of operation.

Other ethically based labelling systems, e.g. the Rugmark Clean Clothes Campaign is not widely used.

B. DEFINITIONS USED IN THE VOLUNTARY INSTRUMENTS

No comments.

C. EXISTING PROHIBITIONS, RESTRICTIONS AND EXEMPTIONS

No comments.

D. VOLUNTARY INSTRUMENTS ACCEPTED/RECOGNISED BY THE AUTHORITIES

The authorities recognize the work of the Finnish Fair Trade Organisation and financial support is given by the Finnish government. Eventually, any ethical claims made will obviously have to be in accordance with the provisions regarding non-misleading information, etc. in the Consumer Protection Act.

IV. VERIFICATION SYSTEMS

A. CRITERIA FOR SUBSTANTIATING CLAIMS

1. Nutritional Claims

The criteria for using nutritional claims are based on the relevant legislation and guidelines discussed in Section II C 1, reflecting the 90/496/EEC Directive and Codex.

As mentioned earlier, any claim appearing on labelling, etc. makes nutritional labelling compulsory. As far as the allowed nutritional claims are concerned, i.e. content and comparative claims, these are based on quantitative criteria. In this way, it is made relatively easy to verify if such claims are justified.

As far as the mentioned nutrient function claims are concerned (in Finland: claims referring to vital functions), guidelines are included in Control 11/99 as discussed earlier. Apart from these guidelines, no particular verification system exists.

2. Health Claims

Acceptable health claims are claims referring to vital functions (based on nutrients, compounds or microbes). Guidelines for permissible claims are included in Control 11/97. Control 11/97 states that permissible claims must be provable. Furthermore, it is quoted that if a claim regards anything but a generally known effect on vital functions, it must be based on sufficient scientific proof. The proof will be evaluated on a case-by-case basis.

3. Ethical Claims

The voluntary system operated by the Finnish Fair Trade Organisation has its own set of principles and criteria corresponding to those of the FLO organisation. The FLO

operates a control/verification system. However, the Finnish authorities are not engaged in any supervision of this system.

B. LEGAL/ADMINISTRATIVE SYSTEMS FOR VERIFYING CLAIMS

The regulatory framework/administrative system concerning labelling and marketing (including claims) consists of the Consumer Protection Act, administered by the Consumer Agency/Consumer Ombudsman and the Food Act, administered by the NFA. Both of these administrative agencies are part of the Ministry of Trade and Industry.

The Consumer Protection Act is relevant for all types of claims including all food related claims whereas the NFA only deals with claims for products regulated by the Food Act. Similarly, claims regarding products under the Medical Act is administered by the Medicinal Agency. In reality, the NFA handles questions relating to both labelling and marketing of food products in accordance with the so-called lex specialis principle.

The municipal/regional authorities handle the concrete labelling of the product whereas marketing in a wider sense (including advertising, etc.) is mainly supervised at a national level, i.e. by the NFA.

The Consumer Agency only gets involved in the marketing of foodstuff cf. the Consumer Protection Act when the Food Act for one reason or another cannot take measures against specific marketing.

1. Pre-Clearance Rules/Guidelines

Questions from companies about food legislation including claims should be addressed to the company's supervisory authority, which is usually the municipal health protection administration.

The NFA publishes guidelines concerning the interpretation of the Food Act and other legislation and is available for advice regarding special cases. However, no pre-clearance mechanism exists in general. When the National Authorities are notified of products regulated by the Directive 89/389 on Foodstuffs for Particular Nutritional Uses, the label (including claims), nutrients, instructions for use, etc. are checked.

2. Post-Clearance Rules/ Guidelines

In most cases, where the regulations are not complied with, the cases are settled in out-of-court procedures. Otherwise, cases may be taken to the civil court and the Market Court. Criminal responsibility will be invoked only in exceptional cases.

Most cases are settled by issuing prohibitions or information orders. These orders can be combined with a fine.

C. LEGAL PERSONS ENTITLED TO TAKE LEGAL ACTION

Any legal person including consumers or competitors can complain to the Consumer Agency or the municipal/regional authority regarding labelling or marketing which is not in accordance with the regulations.

However, as mentioned above the municipal/regional authorities can only take action as far as the labelling is concerned whereas the NFA will take action against any other marketing activities.

D. BURDEN OF PROOF

The burden of proof always rests with the legal person responsible for the marketing of the product and no specific kind of proof is adduced. However, as mentioned under Section IV A 2, so-called claims referring to vital functions should be based on "sufficient scientific proof."

E. APPLICABLE PENALTIES

The applicable penalties when violating claims regulations are usually of limited size, i.e. below EUR 2-4.000. However, fines are rarely used, as the authorities will endeavour to settle any breach of the regulations/guidelines by negotiation.

V. CASE LAW

The NFA directs the market control of all foodstuffs in Finland. According to the NFA, there has not been any decisions or court cases on an inappropriate use of health claims in foodstuffs since 1995 (before 1995 the Consumer Ombudsman had the responsibility for the market control of claims). Since 1995, the NFA has passed comment on unsuitable claims in ten instances. However, in all these cases the claims have been corrected without further action and, therefore, the NFA is not willing to list them.

Before the year 1995 there is one court case (Market Court, MT: 1993:023, 9.11.1993, Ombudsman vs. Valio Oy), where Valio (Finland's biggest dairy company) was prohibited from using the claim that milk cures/relieves/prevents osteoporosis.

There has also been a few cases where health claims have been used in an inappropriate way in the marketing of dietary supplements (for example MT: 1993:008 PSK-Javidox Ab vs. Vitabalans, "High Potency Garlic"). Maybe the most flagrant case was last November when the NFA prohibited the selling and importing of Noni Juice: the seller claimed that the product cures cancer, HIV, diabetes, rheumatism, etc. Press release 21/26.11.1998 is appended.

VI. MEANS OF COMMUNICATION

No differences exist in the applicability of the relevant legislation/guidelines regarding the means of communication used such as television, Internet, press, labels, etc.

VII. STATISTICS ON CLAIMS

Besides information given in Section V Relevant Case Law, no further statistical information is available.

VIII. ANNEXES

1. The Finnish Food Act (Livsmedelslag 361/95) March 17, 1995
2. The Ordinance concerning labelling of foodstuffs (Förordning om påskrifter på livsmedelsförpackninger 794/91) May 10, 1991
3. Decision of The Ministry of Trade- and Industry concerning declaration of nutritional value for foodstuffs (Handels- och Industriministeriets beslut om näringsvärdesdeklaration för livsmedel 1496/93) May 10, 1991
4. Control 11/1997 Medicinal and Health claims in the marketing of foodstuffs (Tilsyn 11/1997 Handbok för tilsynen över påståenden som gäller medicinska egenskaper och hälsan)
5. The Consumer Protection Act (20 January 1978/38).
6. National Food Administration, Press release 21/26.11.1998.

IX. DATABASE OF CONTACTS

F. FRANCE

I. EXECUTIVE ANALYSIS

A. INTRODUCTION

This study on nutritional, health and ethical claims was well received by all interested parties in France. Every person consulted expressed a great interest in the study and collaborated fully in our research.

B. MEMBER STATE POLICY

Whilst a nutritional claim is given a definition in legislation, health claims and ethical claims are not legally defined

1. Nutritional Claims

These are clearly defined in French law, based on relevant EU legislation.

2. Health Claims

Health claims are in line with the current Codex Alimentarius definition guidelines and a Decree provides a specific definition for therapeutic claims, which are forbidden, as per EU legislation 79/112, Article 2. Interestingly, there is an exemption to the general rule banning therapeutic claims, under the Public Health Code. This states that advertisements for products other than medicines that are presented as favouring the diagnostic, treatment or the prevention of a human disease require a "visa de publicité" from the Agence Française de sécurité sanitaire des produits de santé.

The most interesting development to date in France concerns the June 1998 opinion of the Conseil National de l'Alimentation on the use of health claims. This followed extensive consultation with interested parties. The position of the major actors is worth noting since they set the scene for the CNA's recommendations:

- There is a general agreement, shared by consumers, that a foodstuff has an important impact on health. Consequently they wish to learn more about nutrition. However, they are concerned that the current protection provided by law against misleading claims are insufficient and request that the Misleading Advertising Directive should be extended to distance selling and electronic commerce.

- Industry is heavily investing in Research and Development (R&D) to understand the contribution of its products on the improvement of consumers' health and, hence, wishes to advertise the effects through the use of health claims. Industry accepts that, at present, health claims should be limited to claims describing the effects of their products on organic functions (e.g., help the intestinal transit), on a physiologic condition or on the reduction of certain pathologic risks (reduce the risk of cardiovascular diseases). Claims focusing on the treatment or cure of

diseases are not under discussion at present. Industrialists consider that the advertising legislation and the ban on claims relating to a disease are sufficient to protect the consumer. However, they are dissatisfied with the current system of authorising health claims through the Visa PP procedure because it is seen as cumbersome and expensive.

- The scientific community believes that a health claim does not provide sufficient consumer information. Therefore, further information on nutrition is needed in order to put health claims in a more informed context.

The final CNA recommendations include twelve conditions, which need to be met before they will fully accept the development of health claims:

1. The ban of therapeutic claims. It should be noted that the CNA believes that claims focusing on the diagnostic, treatment or cure of a disease should still be forbidden. However, it is ready to accept the following type of claims:
   - A claim suggesting a real contribution of a foodstuff to the prevention of a pathology and presented as "help reduce the risk";
   - A claim suggesting a contribution to the general health condition, and recognised by the scientific community; and
   - Nutritional and functional claims describing the positive role of a nutrient in the normal functioning of the body.
2. The need to apply the same principles to all foodstuff using claims;
3. The use of a trial period, during which an analysis of the impact of the claims would be conducted;
4. The adoption of a comprehensive regulatory framework;
5. A precise system of substantiation of claims;
6. The recognition and the valorisation of the expertise necessary to the substantiation of claims;
7. The adoption of a code of conduct for the communication of claims in the context of the Laws on advertising;
8. The necessity to be rigorous in the application of sanctions for illegal claims;
9. The improvement of the analysis capabilities of consumers, with the collaboration of consumer organisations;
10. The responsible involvement of all actors of the food process;
11. The education of the general public; and
12. The adoption of a real nutrition policy.

Whilst these recommendations have not been followed up, most stakeholders agree that this a sensible way forward and should be used as the basis of a broader European approach to the problem.

3. Ethical Claims

Ethical claims, which are generally understood to be associated with guaranteed human rights in the production phase, are not legally defined and there is no specific legislation in place. Nevertheless, the issue is gaining recognition in France through a major campaign called "de l'éthique sur l'étiquette", which groups together 51 NGOs and consumer associations. The authorities (Ministry of Trade) are of the view that they are not competent to regulate on ethical claims due to WTO requirements. Thus,

they are reviewing the issue to build a consensus that the issue should be debated at either the EU or international level.

C. VOLUNTARY CODES OF PRACTICE

Whilst the CNA Recommendations are helpful, there are still no voluntary instruments, similar to those found in other EU Member States, in place in France. Industry, for its part, is putting considerable emphasis on the role that the CIAA's future voluntary code on health claims may have in better regulating health claims.

The "de l'éthique sur l'étiquette" campaign is a clear signal that whilst on the one hand, consumers are aware of world issues relating to human rights, on the other hand, they are looking not only to government but also to the business community to do something responsible.

The Bureau de verification de la publicité, (the Office for Advertising Verification) is a self-regulatory body whose purpose is to eliminate excessive claims in a pre-clearance system. It provides copy advice, monitors and handles complaints and can issue sanctions. It is deemed to work well and provide flexibility.

D. VERIFICATION SYSTEMS

The "Direction Générale de la Concurrence et de la Repression des Fraudes" (DGCCRF) is responsible for the implementation and the control of the relevant legal instruments, pertaining to nutritional claims, whilst the "Agence Française de Sécurité Sanitaire des Produits de Santé" (AFSSAPS) is responsible for the Visa PP procedure, used for health claims.

In case of nutritional claims, the verification is a posteriori once the product is commercialised as per the requirements of the relevant legislation. In the case of health claims, the Visa PP procedure is a priori, despite the fact that the AFSSAPS is aware of health claims not having sought the Visa PP. If a manufacturer is found not to have requested a Visa PP, the authorities can suspend the product/claim.

The burden of proof, in the case of nutritional claims, lies with the administration to demonstrate that a claim is misleading. In the case of a manufacturer not respecting the visa pp procedure, the burden is on the shoulders of the company to substantiate the claims. In the case of misleading advertising or labelling, infringements to the legislation can led to both fines and/or penal sanctions.

E. MEANS OF COMMUNICATION

There exist any difference between the means of communications.

F. CONSUMER PROTECTION

According to consumer organisations, the protection provided by law against misleading health claims is insufficient. Consumers also believe that Misleading Advertising Directive should extend to new forms of commerce, such as distance selling and electronic commerce.

G. BARRIERS TO TRADE

The Visa PP is sometimes considered to be a heavy procedure and can be perceived as a barrier to trade. This has an impact only on products using health claims.

H. CASE LAW

There is little case law in France on claims as most infringements are examined/negotiated between the manufacturer and the authorities and never reach the court.

I. STAKEHOLDER ANALYSIS

1. Government Authorities

- The conclusion of the debate held by the CNA is the backbone of the current French thinking on health claims. However, no concrete follow-up measures have been taken at national level but the optimal solution seems to lie at the European level.

2. Consumers

- The position of the consumers is best reflected in the consultation process, which took place within the CNA. They agree that a foodstuff has an important impact on health and hence, they wish to learn more about nutrition. However, they are concerned that the current protection provided by law against misleading claims are insufficient and request that the Misleading Advertising Directive should be extended to distance selling and electronic commerce.

3. Industry

- Once again the position of Industry as it relates to health claims is that it invests heavily in R&D to understand the contribution of its products on the improvement of consumers' health and, hence, wishes to advertise the effects through the use of health claims. Industry accepts that, at present, health claims should be limited to claims describing the effects of their products on organic functions, on a physiologic condition or on the reduction of certain pathologic risks (reduce the risk of cardiovascular diseases). Claims focusing on the treatment or cure of diseases are not under discussion at present.

- Industry considers that the advertising legislation and the ban on claims relating to a disease are sufficient to protect the consumer. However, they are dissatisfied with the current system of authorising health claims through the Visa PP procedure because it is seen as cumbersome and expensive.

* * *

II. MEMBER STATE POLICY

A. DEFINITIONS OF CLAIMS

1. Nutritional Claims

The definition of nutritional claims in France is based on article 1 of Directive 90/496/CEE of 24 September 1990 on nutrition labelling of foodstuff, transposed by Decree N°93-1130 in French law.

Article 4 of the Decree states that a nutritional claim is a representation or any form of advertising message that states, suggests or implies that a foodstuff has particular nutritional properties.

A nutritional claim is a claim focusing on the presence, the absence, or the presence at a low or high level of energy or nutriments that a foodstuff may contain.

Claims such as “rich in vitamins” or “low in cholesterol” are considered as nutritional claims in France.

2. Health Claims

For the French administration, health claims indicate, suggest or imply that a relation exists between a foodstuff or a nutrient or a substance contained in a foodstuff and a health condition or a modification of a biological parameter, without any reference to a disease. This is in line with the Codex Alimentarius definition

3. Ethical Claims

There is no legal definition of an ethical claim. Ethical claims are usually associated with a guarantee that human rights have been respected in the production phase of the product.

B. LEGISLATION IN PLACE

1. Nutritional Claims

The provisions of Directive 90/496 on nutrition labelling of foodstuff have been transposed in French law under Decree N° 93-1130 of 27 September 1993 concerning nutrition labelling of foods (Décret N°93-1130 du 27 septembre 1993 concernant l’étiquetage relatif aux qualités nutritionelles des denrées alimentaires).

The Decree provides for:

- The following definition of a nutritional claim: any representation or advertising message that states, suggests or implies that a foodstuff has specific nutritional properties: 1) because of the energy (caloric value) it provides or it does not provide, or it provides in a high or low level; 2) because of the nutrients it contains or it does not contain, or that it contains in a high or low proportion.

- Nutritional claims can only refer to: a) the energetic value of the foodstuff; b) the following nutrients 1) proteins 2) glucides 3) lipids 4) fibres 5) sodium 6) vitamins and minerals.

- The type of information that should be provided to the consumers: quantity of the different nutrients and energy value.

2. Health Claims

Health claims are not precisely defined by French law.

Decree 84-1147 provides for a definition of "therapeutic claims". Article 3 forbids the use of therapeutic claims: "Sous réserve des dispositions applicables aux denrées destinées à une alimentation particulière ainsi qu'aux eaux minérales naturelles, l'étiquetage d'une denrée alimentaire ne doit pas faire état de propriétés de prévention, de traitement et de guérison d'une maladie humaine".

3. Ethical Claims

There is no specific legislation on ethical claims.

C. EXISTING PROHIBITIONS, RESTRICTIONS AND EXEMPTIONS

1. Nutritional Claims

The regime applicable to nutritional claims is detailed in Decree N° 93-1130 of 27 September 1993 concerning nutrition labelling of foods.

The main exemptions to this Decree are mineral water and foodstuffs for particular nutritional uses (as defined by Directive 89/398).

2. Health Claims

- Article 3 of Decree N° 84-1147 of 7 December 1984, implementing the law of 1 August 1905 on frauds and falsifications on products and services relating to the labelling and presentation of foodstuffs, provides that the labelling of a foodstuff cannot claim to prevent, treat or cure a human disease. This type of claims is defined as a therapeutic claim (allégation thérapeutique).

- Article L551-10 of the Public Health Code states that advertisements for products other than medicines that are presented as favouring the diagnostic, treatment or the prevention of a human disease requires a "visa de publicité" from the Agence Française de sécurité sanitaire des produits de santé.

  The Visa PP in this context could be seen as an exemption to the general rule that forbids the use of therapeutic claims.

3. Ethical Claims

There are no specific legal rules prohibiting, restricting or exempting the use of ethical claims.

D. POLICY THINKING AND STAKEHOLDERS' POSITIONS

1. Nutritional Claims and Health Claims

On 30 June 1998, the "Conseil Supérieur de l'Alimentation" published its advice on the use of health claims[1] following a long debate between representatives from industry, consumers, the advertising board and the scientific community which came together in the context of the CNA.

The report is divided into two parts. In the first part, there is an analysis of the current situation and in the second part, concrete recommendations are made.

- Current situation:

The CNA noted that most consumers aspire to a healthier way of life. Consumers are increasingly aware of the role that foodstuffs may play in improving their health condition. This trend has led to the development of health claims. The CNA felt it was necessary to open a debate between the different interested parties in order to recommend new policies to the government.

Position of the different parties:

- Consumers:

Consumers expressed their desire to learn more about nutrition and to extend their knowledge on the role that foodstuffs have on their health. According to the consumer organisations, the protection provided by law against misleading health claims is insufficient. Consumers also believe that Misleading Advertising Directive should extend to new forms of commerce, such as distance selling and electronic commerce.

- Industry:

Industry invests more and more in research and development to understand the contribution of its products in the improvement of consumers' health. The industry wishes to advertise the effects of its products through the use of health claims. Representatives from industry consider that, at present, health claims should be limited to claims describing the effects of their products on organic functions (e.g. help the intestinal transit), on a physiologic condition or on the reduction of certain pathologic risks (reduce the risk of cardiovascular diseases). However, claims focusing on the treatment or cure of diseases are not currently under discussion. Industrialists consider that the advertising legislation and the interdiction of claims relating to a disease are sufficient to protect the consumers. The industry believes that

[1] Conseil National de l'Alimentation; Séance Plénière du 30 juin 1998; avis adopté à l'unanimité; Allégations faisant un lien entre alimentation et santé. Covers nutritional, functional and health claims.

the current system of authorising health claims through the Visa PP procedure is not acceptable[2].

- Scientific experts:

They believe that a health claim does not provide enough information to the consumer and that more general information on nutrition is needed in order to put health claims in a more informed context.

- The CNA proposals:

The recommendation of the CNA covers functional, nutritional and health claims. From a general perspective, all parties believe that health claims could be developed if there was a greater level of information on nutrition amongst the population.

The CNA believes that claims focusing on the diagnostic, treatment or cure of a disease should still be forbidden.

The CNA is ready to accept the following type of claims:

- A claim suggesting a real contribution of a foodstuff to the prevention of a pathology and presented as "help reduce the risk";
- A claim suggesting a contribution to the general health condition, and recognised by the scientific community; and
- Nutritional and functional claims describing the positive role of a nutriment in the normal functions of the body.

The CNA considers that there is a need to adapt the regulatory system and to distinguish between the scientific substantiation of claims and the communication means.

The CNA agreed on the following:

- Therapeutic claims are forbidden;
- Health claims referring to the reduction of a risk should require pre-clearance, except if there are on a positive list established by the authorities;
- Functional claims should be subject to laws on misleading advertising, with a list of authorised claims being verified by a reference organisation external to the company making using the claim.

Generally, all claims subject to a clearance by an external organisation or included on a positive list would be subject to "a posteriori" control.

The CNA believes that a code of conduct should be adopted by the professionals in order to self regulate the form of the claims.

The final recommendation of the CNA contains twelve points that are the necessary conditions to accept the development of health claims:

[2] See V.B.1: Visa PP procedure

- Ban of therapeutic claims;
- The need to apply the same principles to all foodstuff using claims;
- The use of a trial period, during which an analysis of the impact of the claims would be conducted;
- The adoption of a comprehensive regulatory framework;
- A precise system of substantiation of claims;
- The recognition and the valorisation of the expertise necessary to the substantiation of claims;
- The adoption of a code of conduct for the communication of claims in the context of the laws on advertising;
- A requirement to be rigorous in the application of sanctions for illegal claims;
- The improvement of the analysis capabilities of consumers, with the collaboration of consumer organisations;
- The responsible involvement of all actors in the food process;
- The education of the general public; and
- The adoption of a real nutrition policy.

The recommendation has not been followed up until now. Most actors expect that this work will be put into practice in the context of a broader approach at the European level.

The French administration and French consumer organisations do not believe that the current regulatory framework leads to barriers to trade. However, there seems to be a consensus that the Visa PP could be seen as a form of barrier. Nevertheless, most of the people with whom we talked (besides industry) believe that such a procedure might be needed to protect consumers'safety. This question was discussed by the CNA, which concluded that a less stringent "a priori" control could be a solution to the current situation.

2. Ethical Claims

As opposed to "Nordic countries", the issue of ethical claims has not reached the same level of debate in France. However, campaigns from NGO's have managed to obtain results from private companies and public authorities have begun to get involved.

The French Government has recently started to work on the issue of ethical claims. The Minister for trade and the "Direction des relations économiques extérieures" (DREE) are the main actors.

The authorities still consider that they are not competent to regulate on ethical claims. Their view is that due to WTO requirements, the French government cannot regulate on ethical claims as this could be perceived as being a trade barrier. Thus, they consider that any regulatory action should be taken at the level of the WTO or in the context of the International Labour Organisation. The government is now in a preliminary period during which an analysis of the different options at international level is being carried out. The objective of the government would be to build a consensus on the issue at European and International level.

The French government supports voluntary initiatives from the private sector and NGO's. The main campaign in France is entitled "de l'éthique sur l'étiquette". It brings together 51 NGOs and consumer associations, representing most of actors from a consumer perspective. The objective of the campaign is to create a "label social" (social label) guaranteeing consumers that fundamental human rights have been respected in the production chain.

III. VOLUNTARY INSTRUMENTS OR OTHER PRACTICES

A. VOLUNTARY INSTRUMENTS IN PLACE

1. The "Bureau de Verification de la Publicité" (BVP)

The "bureau de verification de la publicité" (BVP) is a self-regulatory body, which has self-regulated advertising for the past 60 years. It is not recognised by the authorities. However, it is a form of "pre-clearance" that eliminates excessive claims.

The BVP's responsibilities are as follows:

- Drawing-up and implementing self-regulatory codes of practice in conjunction with the advertisement industry;
- Advice on and control of advertisements in all media on the basis of relevant legislation and codes of practice; and
- Handling complaints from consumers.

The main activities of the BVP are as follows:

- **Copy advice/Pre-clearance:** Copy advice plays an increasingly important role in the BVP's activities. For television advertising, advertisers are required to submit finished television commercials to the BVP for pre-clearance. The advice of the BVP is binding on the advertiser. For non-television advertising, advertisers and media can voluntarily seek copy advice at the pre-publication stage.

- **Monitoring:** The BVP carries out monitoring of published advertising in all media except television. Monitoring may, in some cases lead to a formal complaint.

- **Complaints handling:** One of the BVP's main tasks is to investigate complaints. These complaints are handled free of charge by a permanent staff of lawyers. Complaints should be addressed to BVP in writing, if possible with a copy of the offending advertisement. If, upon examination, an infringement is apparent, the advertiser is requested either to substantiate his claims or to modify them to comply with the rules. In case of non-compliance with this request, and after notice has been given to the advertiser, the BVP asks the media concerned to cease publication of the advertisement. The BVP publishes its decision in its newsletter, BVP Echos.

- **Sanctions:** The BVP can expel, after a hearing, any member who has failed to comply with its decisions. The BVP can also be party to any court case against those it has found guilty of misleading or otherwise abusing advertising. Other sanctions, which the BVP applies, are formal warnings and adverse publicity.

2. Nutritional claims

There is no voluntary instrument in place.

3. Health Claims

There is no voluntary instrument in place. The industry, with the support of the French administration is involved in the development of a European code of conduct in the context of the CIAA.

4. Ethical Claims

There are several voluntary instruments in place. We have chosen to use the campaign "de l'éthique sur l'étiquette" as our main example considering its importance and the significant number of participating parties (see Section II, B, 3).

B. DEFINITIONS USED IN THE VOLUNTARY INSTRUMENTS

1. Nutritional Claims

There is no voluntary instrument in place.

2. Health Claims

There is no voluntary instrument in place.

3. Ethical Claims

Companies using the social label as defined by the campaign "de l'éthique sur l'étiquette" respect a code of conduct. To adopt the code of conduct and use the social label companies must respect the following ILO conventions:

- Convention N°87 on the freedom of trade unions;
- Convention N°98 on the right of association and collective conventions;
- Convention N°105 on the abolition of forced labour;
- Convention N°111 on non-discrimination of workers;
- Convention N°138 on the minimum required age for employment;
- Conventions N°26 and N°131 on minimum wages;
- Convention N°1 on maximum working time and overtime;
- Convention N°155 on health and safety at the workplace.

The companies must also:

- Promote the code of conduct with their sub-contractors and providers;

- Use all the necessary means to implement the code;
- Participate in an independent control system; and
- Guarantee to consumers that all fundamental human rights have been respected in the processing chain.

C. EXISTING PROHIBITIONS, RESTRICTIONS AND EXEMPTIONS

1. Nutritional Claims

Not applicable.

2. Health Claims

Not applicable.

3. Ethical Claims

Considering the system is based on voluntary agreements there are no prohibitions, restrictions or exemptions. To benefit from a "social label" a company needs to fulfil all obligations laid down in the voluntary agreements.

IV. VERIFICATION SYSTEMS

A. CRITERIA FOR SUBSTANTIATING CLAIMS

1. Nutritional Claims

There is *a posteriori* verification system to substantiate claims. A company wishing to use nutritional claims should forward to the DGCCRF a dossier, which includes (see annex and note from Conseil Supérieur d'Hygiène Publique de France):

- A presentation of the company;
- A general presentation of the product (definition, description, process, qualitative and quantitative production, labelling).

2. Health Claims

Theoretically, a company wishing to use a health claim should obtain a Visa PP from the Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS) before it can use a claim in the labelling or advertising of the product. The visa is delivered by the Director of AFSSAPS after a recommendation from the Committee on the control of advertising[3].

However, it appears that a number of products using health claims have recently been put on the market without any Visa PP.

[3] See annex on the "recommendations pour la constitution des dossiers" – Direction des études et de l'information pharmaco-economiques – Agence Française de Sécurité Sanitaire des Produits de Santé.

3. Ethical Claims

The criteria are defined by the obligation of the code of conduct, which refers to several ILO conventions (see above). The objective of the campaign "de l'éthique sur l'étiquette" is not to certify a product and the claim attached but to certify the production plants of the manufacturer, which could then claim a social label.

Until now, the campaign has approached the French authorities (Minister of consumer affairs) to see whether they could participate in the definition of a certification system (type ISO).

B. LEGAL/ADMINISTRATIVE SYSTEMS FOR VERIFYING CLAIMS

The "Direction Générale de la Concurrence et de la Repression des Fraudes" (DGCCRF) is responsible for the implementation and the control of the relevant legal instruments. The "Agence Française de Sécurité Sanitaire des Produits de Santé" (AFSSAPS) is responsible for the visa pp procedure.

1. Pre-Clearance Rules/ Guidelines

a. Visa PP procedure[4]

According to the French health code (articles L. 551-10, L. 556, R.5052 to R.5052-3), advertisements for products presented as beneficial for health have to be approved by the Director of the AFSSAPS before the product is put on the market.

According to AFSSAPS, the following products have to follow this procedure:

- Products favouring the diagnosis, the prevention or the treatment of human diseases;
- Products favouring the diagnosis or the modification of the physical or physiological state.

The manufacturer or the distributor of the product must request a visa for every form of advertising: packaging, labelling, brochure, TV or radio advertisement etc…The AFSSAPS collects a tax of 3000 FF (approx. EUR 457) on every Visa PP.

The dossier must include:

- A covering letter indicating the type of advertisement;
- A completed form (see annex);
- A photocopy of the advertisement;
- An example of packaging;
- A dossier on the substantiation of the claim including the composition of the product, and a scientific dossier substantiating the claims.

[4] Demandes de "Visas PP" – Recommandations pour la constitution des dossiers – Agence Française de Sécurité Sanitaire des Produits de Santé – April 1999

b. Clearance system defined on nutritional claims[5]

A dossier has to be submitted to the DGCCRF and must include:

- Information on the producer;
- Definition of the product;
- Description of the production process;
- Qualitative and quantitative composition
- Labelling.

2. Post-Clearance Rules/ Guidelines

- Although the Visa PP is normally a pre-clearance procedure, a lot of products are put on the market without the approval of AFSSAPS. If a product using claims without a Visa PP is identified by AFSSAPS, the producer or the distributor is requested to fill up an application for the visa. In certain cases, the marketing of the product might be suspended.

3. What are the administrative/legal costs?

A tax of 3000 FF (approx. EUR 457) is collected for each Visa PP

C. LEGAL PERSONS ENTITLED TO TAKE LEGAL ACTION

- Any legal or natural person considering that a nutritional or health claim is illegal is entitled to take legal action. The person can directly address the complaint to the judiciary system or to the administration, which can address the complaints to the relevant judiciary institutions after a preliminary inquiry.

- On the basis of local enquiries the DGCCRF can start redress procedures on the basis of misleading advertising.

- On the basis of local enquiries the AFSSAPS can start redress procedures.

- If a health claim is being used without a Visa PP, the AFSSAPS can suspend the marketing of the product until the producing company can substantiate the claim being made.

D. BURDEN OF PROOF

1. Burden of proof

- In the case of nutritional claims, the burden of the proof belongs to the administration. It has to demonstrate the misleading aspect of the advertisement of the label.

[5] Conseil Supérieur d'Hygiène Publique de France – Section de l'alimentation et de la nutrition – Groupe de travail "Valeur Nutritionnelle" – proposition sur les éléments à fournir par un pétitionnaire pour l'analyse des docciers par le groupe de travail.

- If a company has not respected the procedures of the Visa PP, it must substantiate its claim.

2. Proof to be adduced

See Visa PP procedures.

E. APPLICABLE PENALTIES

In the case of misleading advertising or labelling, infringement to the legislation in place may lead to fines or to penal sanctions (up to two years imprisonment and/or 250 000 FF (approx EUR 38 112) fine and the publication of the judgement).

The Visa PP is sometimes considered to be a heavy procedure and can be perceived as a barrier to trade. However, the administration believes that a pre-clearance procedure (although it could be lighter than the one in place at the moment) is necessary to guarantee consumer protection.

V. CASE LAW

1. Nutritional Claims

No relevant case law.

2. Health Claims

There are only a few cases in France. The best example is provided by C. Paris (13eme Ch. Sect. A) 5 February 1997: Teillard d'Evry vs. Ms Petit.

During a control carried out by the DGCCRF, the authorities established that the labelling of certain foodstuff was using health claims as defined by article L551 of the Health Code. The claims were "convient à toute personne souhaitant renforcer son dispositif cérébral", "accélère la perte des surcharges graisseuses", "effets laxatifs incontestables" etc…

The companies never requested a Visa PP as provided in article L 551.

The judge considered that these claims were more than a precision to the list of ingredients and, therefore, considered that they should be subject to the Visa PP procedure.

3. Ethical Claims

There is no specific case law.

VI. MEANS OF COMMUNICATION

There are no real differences between means of communication.

VII. STATISTICS ON CLAIMS

We could not find any relevant statistics.

VIII. ANNEXES

- Loi N°86-1067 du 30 septembre 1986 relative à la liberté de communication.
- Décret N°93-1130 du 27 septembre 1993 concernant l'étiquetage relatif aux qualités nutritionnelles des denrées alimentaires;
- Arrêté du 3 décembre 1993 portant application du décret N°93-1130 du 27 septembre 1993 concernant l'étiquetage relatif aux qualités nutritionnelles des denrées alimentaires.
- Décret N°92-280 du 27 mars 1992 pris pour l'application du paragraphe 1 de l'article 27 de la loi du 30 septembre 1986 relative à la liberté de communication et fixant les principes généraux concernant le régime applicable à la publicité et au parrainage;
- Décret N°84-1147 du 7 décembre 1984, portant application de la loi du 1er Aout 1905 sur les fraudes et falsifications en matière de produits ou de services en ce qui concerne l'étiquetage et la présentation des denrées alimentaires.
- Décret N°96-531 du 14 juin 1996 relatif à la publicité pour les médicaments et certains produits à usage humain et modifiant le code de la santé publique (deuxième partie: Décrets en Conseil d'Etat).
- Décret N° 99-144 du 4 mars 1999 portant transfert de compétences au profit de l'agence française de sécurité sanitaire des produits de santé et modifiant le livre V du code de la santé publique (deuxième partie: Décrets en Conseil d'Etat).
- Code de la Consommation (Partie Législative) – Section 1: Publicité – Articles L 121-1 to L 121-15;
- ode de la Consommation (Partie Législative) – Section 1: Tromperie – Articles L 213-1 to L 213-2;
- Code de la Consommation (Partie Réglementaire) – Livre 1: Informations des consommateurs et formation des contrats – Article R 112-7.
- Code de la Santé Publique (Partie Législative) – Chapitre 4: Réglementation de la publicité – Articles L551 to L556.
- Code de la Santé Publique – Article R.5046-1
- Avis du Conseil National de l'Alimentation adopté lors de sa séance plénière du 30 juin 1998 concernant les allégations faisant un lien entre alimentation et santé.
- Proposition sur les éléments à fournir par un pétitionnaire pour l'analyse des dossiers de demande d'autorisation d'allégations nutritionnelles – Conseil Superieur d'Hygiène Publique de France.
- Dossier from the campaign "de l'éthique sur l'étiquette";
- Receuil de fiches de recommandations pour les publicités en faveur des produits présentés comme bénéfique pour la santé. Ministère du travail et des affaires sociales. Commission de contrôle de la publicité.
- Avant-projet de recommandations concernant les allégations relatives à la santé – observations de la France à l'étape 3.

- Avis du 18 décembre 1996 de la CEDAP sur les recommandations relatives au caractère non trompeur des allégations nutritionnelles fonctionnelles.

IX. DATABASE OF CONTACTS

G. GERMANY

I. EXECUTIVE ANALYSIS

A. INTRODUCTION

This study on nutritional, health and ethical claims was generally well received by all interested parties in Germany. All contacted parties were willing to provide an input to the study. There was a general opinion that something needed to be done on health claims.

The following Executive Analysis outlines the key points of interest for the purpose of the study.

B. MEMBER STATE POLICY

1. Nutritional Claims

The definition of a nutritional claim is very similar to the one used in EU law. Nevertheless, German law does not foresee the possibility to make a claim on the energy or nutrient value that the foodstuff does not provide or contain.

From the authorities point of view, current legislation on nutritional claims is satisfactory and no new initiatives are currently planned. The Food Industry Association felt that in some cases the 15% RDA rule for vitamin and mineral claims was too restrictive.

2. Health Claims

With regard to health claims, Germany implemented word by word Directive 79/112. But in addition further provisions are made under German law, which somewhat extend the prohibitions of Directive 79/112.

The Ministry of Health felt that in principle it was not harmful to allow manufacturers to make statements, which were scientifically proven. This could eventually also include disease risk reduction claims. Nevertheless, if such claims were to be permitted, one would quickly reach the borderline with pharmaceutical products. In Germany, the authorities were, therefore, giving a wide definition to pharmaceuticals in order to reduce the danger of self-medication and to avoid the situation where the consumers might believe that foodstuffs have the same effects as medicines.

The main German Consumer Association felt that EU legislation may be necessary, as more and more functional foods, food supplements and probiotic foodstuffs were coming on the market, which were primarily using claims.

The Food Industry Association is in favour of an amendment to Directive 79/112, in order to allow disease risk reduction claims. Industry and authorities considered that before legislating on health claims, it was necessary to define at EU level the term

foodstuffs, as otherwise the question would always appear as to whether a specific product was a foodstuff or not.

3. Ethical Claims

The issue of ethical claims has received only limited attention by the authorities in Germany. There is no legal definition of an ethical claim and no directly relevant legislation.

C. VOLUNTARY CODES OF PRACTICE

1. Nutritional and Health Claims

No voluntary instruments exist in Germany on health or nutritional claims. While the Food Industry had reflected on a code of conduct with consumer groups, it felt that a code of conduct would not resolve barriers to trade, as German courts would eventually continue their strict application of Directive 79/112. The main Consumer Association considered that a code of conduct might be used as an excuse not to legislate.

Having said that, the German Advertising Council, which is the self-regulatory body of the German advertising industry has developed guidelines on the advertising of alcoholic beverages, which re-inforce prohibitions on health claims contained in Directive 79/112 and in particular in Directive 89/552 on TV without Frontiers.

2. Ethical Claims

There exist a number of labelling schemes with regard to ethical claims. The most well-known is the one administered by TransFair, which acts as an independent organisation selling licences for the use of its TransFair-Seal. In the licensing agreements that TransFair concludes with companies, it sets out the text that companies have to use on the backside of their label. This text usually contains a number of ethical claims.

D. VERIFICATION SYSTEMS

With regard to the criteria for substantiating claims, the only ones that apply are those set out in the law on nutritional labelling and for dietary foods the ones as set out under the notification procedure of dietary foods apply. In addition, the Federal Health Office has drafted a position paper on sports foods, which is used as an internal guideline and which states that claims made have to be factually correct and scientifically sound.

Pre-clearance is considered censorship and is, therefore, not applied in Germany. Nevertheless, there exist some informal arrangements, which allow companies to verify their claims with the relevant surveillance authorities.

As to post-clearance, this is in general done by the food and medicine surveillance authorities in the German regions. They routinely carry out checks. In addition, there exist a number of out-of-court procedures. The Centre for Fight against Unlawful

Competition serves as a contact point for consumers. The Centre can bring such complaints - if necessary - to settlement points established within the chambers of commerce. Another out-of-court procedure dealing more specifically with immoral, unethical, sexist etc. advertising is run by the Advertising Council.

As to the burden of proof, it lies with the complainant under the Law on Unfair Competition, as well as the Food Law. Nevertheless, the Federal Court concluded in several judgements that the burden of proof was with the defendant where he was using an opinion, which is controversial amongst experts. This is without mentioning the dissenting scientific view. Nevertheless, consumer associations seem to experience problems with claims that cannot be scientifically proven. It appears difficult for consumer associations to find and finance an expert who could provide an opinion proving that the claim cannot be scientifically proven. Therefore, many cases are not brought to court.

Penalties can range from small fines to imprisonment. Misleading advertising is punished under law more severely than forbidden health claims.

E. MEANS OF COMMUNICATION

There is no difference between means of communication, although the Internet, whilst not proving to be an actual problem yet, is seen as a potential problem.

F. CONSUMER PROTECTION

The Ministry of Health felt that German legislation was sufficient in terms of consumer protection. It indicated, nevertheless, that the law did not address the problem that food companies were sometimes using selective statements, which were true in themselves, but without putting them into context. In its answer of October 1996 to a Commission request for information on miracle products, the German Government indicated that the surveillance instruments available may be less efficient with regard to door to door and mail-order selling.

The main Consumer Association indicated that there were problems of consumer protection. In particular, there seemed to be problems with regard to probiotic foodstuffs, functional foods and food supplements, as food manufacturers were in these cases trying to check out the limits of the prohibition of disease related claims. In the consumer association's view, it was necessary to regulate as to which claims may be used under which conditions. The association also indicated that there were some more subtle forms of claims, which were either not regulated by law, or which the surveillance authorities did not pursue, e.g. food companies sponsoring certain health related TV series.

The Centre for Fight against Unlawful Competition (which is a private association acting against unlawful competition, including claims) considered that German legislation provided for adequate consumer protection. Nevertheless, a problem area was food supplements, as the current legislation did not seem to be fitted for these products, which seemed to be neither a foodstuff nor a medicine.

From the statistical information we were able to gather, it appears that the Centre for Fight against Unlawful Competition receives with regard to food-related claims around 100 complaints per year. The Consumer Protection Association's database that goes back to 1992, indicates that it has sent around 150 complaints to companies with regard to health related advertising. Out of these, 80 concern advertising for slimming products.

The authorities, industry and consumer associations indicated that there had not been any problems in terms of consumer protection regarding fair trade labelling schemes.

G. BARRIERS TO TRADE

In the Ministry of Health's view, there exist no significant barriers to trade with regard to health claims. It acknowledges that sometimes problems arose with regard to the import of food supplements, as these were often defined as a medicinal product in Germany simply because of the claims made.

The Food Industry Association indicated that in practice it was difficult to find barriers to trade, as German legislation on health claims was already one of the most restrictive in the EU and also because companies would in general try to adapt to national labelling rules instead of bringing such issues to the courts.

The authorities, industry and consumer associations indicated that there had not been any problems in terms of barriers to trade regarding fair trade labelling schemes.

H. COURT CASES

There exist a considerable number of court cases in Germany, in particular with regard to health claims. German courts interpret health claims restrictively, i.e. even if a reference is not explicitly made clear to a certain illness it was sufficient to use a clear paraphrase of an illness, or where the symptoms described made a clear reference to a specific sickness. The court cases also indicate the reasoning for the courts' strict interpretation of health claims. This is mainly done for two reasons: - to avoid the danger of self-medication and to avoid consumers believing that foodstuffs have the same effects as medicines.

I. STAKEHOLDER ANALYSIS

There is a general view that with the development of new products, such as dietary supplements and probiotic foods, authorities need to look into the issue of claims. There seems to be a general agreement that voluntary codes are not a viable way in Germany to address the issue.

In conclusion, the positions of the main stakeholders are:

1. Government Authorities

- On nutritional claims, the authorities see no need for review.

- On health claims, although the authorities consider that the current situation is satisfactory, they indicated that because of the borderline with medicines an EU definition of the term foodstuffs was necessary, before legislating on health claims. If the EU saw a need to address health claims, this should be done via an amendment to Directive 79/112.

- On ethical claims, there is no real position.

2. Consumers

- Consumers consider legislation on claims necessary, in particular due to the increasing sale of functional foods, food supplements and probiotic foodstuffs. The burden of proof should in their view be shifted to the manufacturer. There is not yet a clear view on pre-clearance vs. post-clearance amongst the consumer associations.

3. Industry

- The food industry is of the opinion that EU rules on health claims needed to be adapted via an amendment to Directive 79/112. Disease risk reduction claims should be allowed, while claims on the treatment and curing of diseases should remain prohibited. Food industry also considers it necessary to define the term foodstuff at EU level.

- With regard to nutritional claims, it is considered that the 15% RDA value in order to be able to make a claim should be reviewed.

- On ethical claims, the overall view of all parties is that there is no need for legislation.

*** * ***

II. MEMBER STATE POLICY

A. DEFINITIONS OF CLAIMS

1. Nutritional Claims

The definition of nutritional claims is provided in article 1, paragraph 2 of the German nutrition labelling decree (Verordnung zur Neuordnung der Nährwertkennzeichungsvorschriften für Lebensmittel, BGBl. I 1994 S. 3256, Annex 1) implementing the EU Nutrition Labelling Directive 90/496. The definition is the same as the one used in the EU Directive 90/496.

It reads: "1. Nutritional claims: any representation or message used in advertising or marketing of foodstuffs, which states, suggests or implies that a foodstuffs has particular nutrition properties due to the energy or nutrient value it possesses".

It is interesting to note that 'nutritional claim' has been translated into German literally as a 'nutrition property related indication'. From this has to be distinguished nutrition labelling, which literally has been translated in German as 'nutrition property related labelling'.

The definition of a nutritional claim is very similar to the one used in EU law. Nevertheless, German law does not foresee the possibility to make a claim on the energy or nutrient value that the foodstuff does not provide or contain.

2. Health Claims

German law does not contain any definition of health claims. Nevertheless, by default, the law forbids medical claims and provides for a narrow interpretation of health claims. Under the German Food Law (Lebensmittel- und Bedarfsgegenständegesetz, BGBl. I 1997 S. 2296, Annex 2), paragraph 18 states that:

"[…] it is prohibited when marketing foods or when advertising foods in general or in individual instances:

1. to use statements referring to the elimination, alleviation or prevention of sickness [same as Article 2 of 79/112],
2. to make reference to medical recommendations or medical expertise,
3. to feature or refer to case histories',
4. to feature or refer to statements by third parties, particularly letters of thanks, recognition or recommendation insofar as they refer to the elimination or alleviation of illnesses,
5. to show pictures of people wearing a uniform of the medical profession or in the process of carrying out an activity reserved for members of the medical, nursing or pharmacological professions,
6. to use statements capable of arousing or exploiting people's fears,
7. to feature documents or written information instructing people to treat illnesses with foodstuffs."

The German Food Law is, therefore, similar to Article 2 of the EU Labelling Directive 79/112, in that it does not allow the claim that a foodstuff has the property of preventing, treating, or curing a human disease. However, a number of further provisions are made, which extend the prohibitions of Directive 79/112 (see points 2. to 7. in paragraph 18 of the German Food Law listed above), thereby establishing a more restrictive interpretation of 79/112.

As for nutritional claims, the term claim seems to be linked to the 'marketing' and/or 'advertising' of a foodstuff, while for labelling terms such as 'denomination', 'indication' and 'presentation' are used (see paragraph 18 point 5).

In addition, the German Food Law provides for a general prohibition to market or advertise foodstuffs in a misleading manner (paragraph 17 alinea 5). The Food Law gives three examples, which can be considered as misleading:

- if a foodstuff claims to have certain effects, which are either not proven by science or are not proven by sufficient scientific evidence;
- if a foodstuff is given the appearance of a medicinal product; and
- if expressions, indications, presentations, or other statements are used to mislead about the origin, the quantity, the weight, the date of production, the date of best before or any other circumstance, which are determinant for the judgement of the product.

Under German Food Law, certain enhanced function claims, as defined under the latest Codex draft recommendations for the use of health claims, could be permitted (see IV. A) 2.). However, diseases risk reduction claims as defined under the same Codex draft are clearly not permitted under German law.

3. Ethical Claims

German legislation does not contain any definition of ethical claims.

B. LEGISLATION IN PLACE

1. Nutritional Claims

EU Directive 90/496 on Nutrition Labelling of Foodstuffs has been implemented in Germany via the nutrition labelling decree (Verordnung zur Neuordnung der Nährwertkennzeichnungsvorschriften für Lebensmittel, Annex 1). This decree also contains provisions for a number of nutritional claims, which are not foreseen in the EU Directive (see II. D) 1) b)).

The EU Directive 89/398 on Foodstuffs for Particular Nutritional Uses was implemented via the decree for dietary foods (Verordnung über ditätetische Lebensmittel, Annex 7).

Specific legislation exists for claims made on milk products (Verordnung über Milcherzeugnisse, Annex 6) (see II) D) 1) b)).

EU Directive 80/177 on mineral waters has been implemented via the decree on mineral and table waters (Annex 5), which contains a list of nutritional claims that can be made (see II) D) 1) b)).

2. Health Claims

The relevant parts of EU Directive 79/112 on Labelling of Foodstuffs dealing with health claims have been implemented via the Food Law (Lebensmittel- und Bedarfsgegenständegesetz, Annex 2).

The German decree for dietary foods (Annex 1) also contains some provisions regarding specific health claims (see II) D) 2) c)).

The EU Directive 84/450 on Misleading Advertising was implemented in Germany via the law on unfair competition (Gesetz gegen den unlauteren Wettbewerb, Annex 8).

EU Directive 89/552 on Television Broadcasting was implemented via the Federal Broadcasting Agreement (Rundfunkstaatsvertrag, Annex 16), as well as guidelines of the German Advertising Council on alcohol advertising (Verhaltensregeln des Deutschen Werberates über die Werbung und das Teleshopping für alkoholische Getränke, Annex 10).

3. Ethical Claims

There exists no specific legislation in Germany on ethical claims. For ethical claims used on foodstuffs the Food Law therefore applies, and in a more general manner the law on unfair competition applies.

C. EXISTING PROHIBITIONS, RESTRICTIONS AND EXEMPTIONS

1. Nutritional Claims

a. Prohibitions

Under article 1 paragraph 6 point 1 of the German nutrition labelling decree (BGBl. 1994 I S. 3526, Annex 1), it is forbidden "in the marketing or advertisement of foodstuffs to use designations, indications or presentations, which suggest that a foodstuff has slimming properties or acts as an aid to slimming or weight reduction".

This provision does not apply to foodstuffs that are intended to be used as a daily ration for overweight people (see below under c)).

b. Restrictions

Under article 1 paragraph 2 of the German nutrition labelling decree (BGBl. 1994 I S. 3526, Annex 1), nutritional claims may only refer to the energy value and/or the content of protein, carbohydrates, fats and saturates, as well as substances which are part of these groups of nutrients (including cholesterol). Furthermore claims relating to salt can be made.

Claims regarding the vitamin and mineral content are restricted to the following nutrients: vitamin A, B1, B2, B6, folic acid, pantothenic acid, niacin, vitamin B12, C, D, E, biotin, calcium, phosphor, iron, magnesium, zinc and iodine. Such claims can only be made if the vitamins are contained to a significant amount in the foodstuff, i.e. 15% of the RDA (nutrition labelling decree, article 1, para 4., point (2), alinea 6.)

There are also a number of restrictions in the German nutrition labelling decree regarding low-energy and reduced-energy claims (article 1, paragraph 6, point (2) alinea 1 and 2). No reference may be made in marketing or advertising of foodstuffs to the low energy value of a food if:

- in the case of foods other than drinks, soups or broths, the energy value amounts to more than 210 kJ or 50kcal per 100g of the ready-to-consume product; or
- in the case of drinks, soups and broths, the energy value amounts to more than 84 kJ or 20kcal per 100ml of the ready-to-consume product.

No reference may be made in marketing or advertising of foodstuffs to the reduced energy value of a food if the energy values per 100g listed in Annex II for a number of foodstuffs (bread, cake, meat products etc.) are exceeded. For the foodstuffs not listed in Annex the energy value has to be at least 40% below the average energy value of comparable foodstuffs, in order to be able to make a reduced-energy claim. The Ministry indicated that this applied to 'light' claims.

Furthermore, restrictions apply with regard to reduced-nutrient content claims. Reduced nutrient content claims are only allowed if the nutrient content is at least 40% less than the average nutrient content of comparable foodstuffs. An exception is made with regard to reduced carbohydrate claims for bread and bakery products. The reference value here is 30% (paragraph 6, point 3a of the nutrition labelling decree).

Finally, restrictions apply with regard to sodium claims. It is permissible to refer to a reduced sodium content only for a number of foods (listed in Annex III of the decree: bread, bakery products, soups, sauces, products from fish, cheese etc.) and only if a limit value of 250mg per 100g is not exceeded (article 1, paragraph 6, point (2) alinea 3b).

Reference should not be made to a low salt or sodium content, if in the case of food products other than beverages, the sodium content is more than 120mg per 100g of the ready-to-eat product. In the case of beverages, the sodium content should not be more than 2mg per 100ml of the ready-to-drink product (article 1, paragraph 6, point (2) alinea 4).

There exists specific legislation with regard to the composition and labelling of two products: mineral waters and milk based products.

With regard to mineral waters, the decree on mineral and table waters (BGBl I 1984, S. 1036, Annex 5) establishes in Annex 4 the allowed nutritional claims. Thus, specific limits have been set for low mineral content, extra low mineral content and high mineral content claims (500mg/l, 50mg/l and 1500mg/l respectively).

Furthermore, only for a limited number of minerals is a content claim allowed, and for these minerals certain threshold values have been established. Thus only claims regarding bicarbonate, sulfate, chloride, calcium, magnesium, fluoride, iron and sodium are allowed.

Finally, the decree fixes that the claim 'suitable for a diet poor in sodium' can only be made for mineral and table waters with a sodium content that is below 20mg/l.

With regard to milk based products, a decree from 1970 covering these products (BGBl. 1970 I, S. 1150 as last amended in 1990, Annex 6) establishes in its Annex the sales names for milk based products (ranging from sour milk products over mixed milk drinks to cheese products) and the criteria that have to be fulfilled for being able to use these sales names. The term 'low-fat' forms part of the sales name and a maximum fat content is established for each low fat product, e.g. low-fat yoghurts can only have a fat content between 1.5 and 2.0% per 100% of its weight.

c. Exemptions

Two exemptions exist regarding slimming claims (nutrition labelling decree paragraph 6 point (3)). Firstly, under the nutrition labelling decree (Annex 1), it is possible to refer in restaurants for the main meal that has an energy value below 2100 kJ or 500 kcal as "for a weight control diet".

Secondly, for the marketing and advertising of foodstuffs that are intended to be used as a daily ration, reference to a low or reduced energy value may only be made if these products fulfill the composition criteria listed in the German decree on dietary foods (Verordnung über diätetische Lebensmittel, BGBl. 1988 I S. 1713, last amended in 1996, Annex 7), where a number of energy values and vitamin and mineral content criteria are listed (paragraph 14a)

2. Health Claims

a. Prohibitions

As indicated under the definition of health claims, these are defined very narrowly in Germany (see II.A) 2)). Apart from this narrow definition, no further prohibitions are mentioned under German law.

b. Restrictions

See again the definition of health claims mentioned above (under II. A) 2)).

c. Exemptions

Although medical claims are in general forbidden, the German decree on dietary foods (Verordnung über diätetische Lebensmittel, Annex 7) allows the use of certain medical claims for dietetic foodstuffs (which are defined as under the EU Directive 89/398 on Foodstuffs for Particular Nutritional Uses). Paragraph 3 of the dietary foods decree indicates that as an exception to the German Food Law, certain statements referring to the elimination, alleviation or prevention of sickness are allowed.

These statements are the following:

'dietetic foodstuff suitable for the treatment of infant dyspepsie, only in the framework of the medical decree"

'dietetic foodstuff suitable for the treatment of congenital metabolic disorders'
liver insufficiencies"
kidney insufficiencies'

Furthermore, statements can be made regarding foodstuffs that may be used in the special diet in case of:

- maldigestion or malabsorption;
- food intake troubles;
- mellitus;
- chronically inflamed intestines, or pre- or post operative treatment of intestinal operations;
- chronic pancreatitis; and
- gout.

In these cases, the statement has to be used: 'for the special diet in case of … in the framework of a diet plan'.

Furthermore, the restrictions applying to health claims as defined in paragraph 18 of the German Food Law do not apply to advertising which is addressed to members of the medical or nursing professions (paragraph 18, point 2).

3. Ethical Claims

a. Prohibitions

As no specific legislation exists for ethical claims, the general law against unfair competition applies (RGBl. 1909, S. 499, last amended in 1998, Annex 8). Notably paragraph 3 of the law states that:

"Who in commercial activities makes for competitive purposes misleading statements over the commercial conditions, in particular the nature, the origin, the production method or the price determination of individual products […] can be claimed for injunction of statements."

Furthermore, the general interdiction of misleading claims under the German Food Law applies (see paragraph 17, alinea 5).

b. Exemptions

As no specific legislation exists for ethical claims, no exemptions are foreseen under German law.

c. Restrictions

As no specific legislation exists for ethical claims, the general restriction of the law against unfair competition (see point a) above) apply. Furthermore, the general interdiction of misleading claims under the German Food Law applies (see point a) above).

D. POLICY DEVELOPMENTS AND STAKEHOLDERS' POSITIONS

1. Nutritional Claims

The German authorities consider current legislation on nutritional claims to be satisfactory and there are no new initiatives in the pipeline.

The Ministry of Health indicated that there sometimes existed problems in terms of whether a nutritional statement on the label could be considered a nutritional claim or was part of the ingredient list. But this seems neither to have lead to any barriers to trade or consumer protection problems.

The German Food Industry Association indicated that in general there were neither barriers to trade nor consumer protection problems with regard to nutritional claims. The association gave, nevertheless, two examples where German nutrition labelling legislation was working against the consumer:

- Under the nutrition labelling decree vitamin and mineral claims can only be made if the amounts were above a level of 15% of the RDA. But for some drinks it was not possible reach such high mineral values, without leading to taste problems of the product.
- For several milk products it was impossible to make a calcium claim for the same reason, i.e. 15% of the RDA of calcium would sometimes significantly change the taste of the product. Not being able to make a calcium claim on milk products was in the association's view rather absurd, as milk was one of the most significant providers of calcium.

In these cases, the 15% value should, therefore, be reduced, in order to being able to make a claim.

2. Health Claims

The current policy thinking of the Ministry of Health is that in principle it was not harmful to allow manufacturers to make statements, which were scientifically proven. This could eventually also include disease risk reduction related claims. Nevertheless, if such claims were to be permitted, one would quickly reach the borderline with pharmaceutical products. In Germany, the authorities are giving a wide definition to pharmaceuticals in order to reduce the danger of self-medication and to avoid that consumers might believe that foodstuffs have the same effects as medicines.

Because of the borderline with medicines, the Ministry of Health feels that it is necessary first to define at EU level the term foodstuffs, before legislating on health

claims at EU level, otherwise the question would always appear as to whether a specific product was a foodstuff or not.

As to defining a health claim, the Ministry is not entirely convinced as to whether a definition is needed, as a claim was in essence advertising (consequently, the EU Directive on Misleading Advertising would cover claims). They suggested that eventually a claim could be defined negatively (i.e., not the sales name nor the ingredients listing).

If the Commission felt that health claims needed to be regulated, in the Ministry's view this should be regulated via an amendment to Directive 79/112.

The main German consumer association (Arbeitsgemeinschaft der Verbraucherverbände) felt that EU legislation may be necessary, as more and more functional foods, food supplements and probiotic foodstuffs were coming on the market (see Annex 3), which were primarily using claims. In its view, a regulation such as in the US or the Swedish code of conduct may be a way forward.

The German Food Industry Association (Bund für Lebensmittelrecht und Lebensmittelkunde) is of the opinion that EU rules on health claims needed to be adapted via an amendment to Directive 79/112. In the association's view claims on disease risk reduction should be allowed, while claims on the treatment and curing of diseases should remain prohibited (see materials from press conference of BLL of 6 May 1999, Annex 4).

The association indicated that in this context there was a need to define what is a foodstuff at the EU level. This was in particular necessary as the differentiation between a foodstuff and a medicine was often made based on the claim used. Basing the differentiation on the claim made should only apply when it was clear that a certain product could eventually fall in one or the other category. But where a product was in its substance clearly a foodstuff, then even a strong health claim should in the association's view not make it a medicinal product.

In addition, a definition of the term health claim was in the association's view also needed, as discussions in the Codex Alimentarius had shown that the understanding of the term health claims differed sometimes (some seemed to understand health claims in the sense of disease related claims, others purely as health related claims and others seemed to consider under the same term both).

The Centre for Fight against Unlawful Competition (Zentrale zur Bekämpfung unlauteren Wettbewerbs), which is a private association acting against unlawful competition, including claims (for further details see V) B. 2) c)), was of the opinion that EU legislation may be needed in the area of food supplements, as current legislation was not adequate for these products. Nevertheless, it felt that a specific definition of claims was not necessary, as at least in Germany advertising was interpreted quite widely, thus covering claims.

The Ministry of Health is currently working on legislation for food supplements, which will also include some labelling rules. The Ministry indicated that these

provisions would be in line with EU legislation and notably 79/112, i.e. illness related claims would not be allowed.

In the Ministry of Health's view, there existed no significant barriers to trade with regard to health claims. Germany was following Directive 79/112. If other Member States were to allow illness-related claims, they would be in contradiction with EU law. The import of such products could, therefore, be blocked under EU law.

Furthermore, the Ministry felt that barriers to trade had most often to do with the composition of a product. While a manufacturer had in any case to change the language of his label when crossing the border, it was felt that it was not a major problem to eventually change the claim accordingly. It was on the other hand much more difficult to change the composition of a product. Nevertheless, the Ministry also indicated that some uniform rules as to how article 2 of 79/112 should be interpreted would bring some legal certainty.

The Ministry, nevertheless, acknowledged that there were sometimes problems in terms of free movement of goods with regard to food supplements. This was due to the fact that food supplements were often defined as a medicinal product in Germany, simply because of the claims made.

In terms of consumer protection, the Ministry felt that German legislation was sufficient (for more remarks on consumer protection see following chapters).

The German Food Industry Association mentioned that it was in practice difficult to find barriers to trade with regard to Germany, because German legislation on health claims was already one of the most restrictive ones in the EU and also because companies would in general try to adapt to national labelling rules instead of bringing such issues to the courts.

The Centre for Fight against Unlawful Competition (Zentrale zur Bekämpfung unlauteren Wettbewerbs), which is a private association acting against unlawful competition, including claims (for further details see V) B. 2) c)) believes that German legislation provides for adequate consumer protection. Nevertheless, it felt that a problem area was food supplements, as the current legislation did not fit these products, which seemed to be neither a foodstuff nor a medicine.

In terms of legislation, the main German consumer association (Arbeitsgemeinschaft der Verbraucherverbände) considers that there are especially problems with regard to probiotic foodstuffs, functional foods and food supplements, as food manufacturers were in these cases trying to check out the limits of paragraph 18 of the Food Law, which defines in more detail the prohibition of disease related claims. In the consumer association's view, it is necessary to regulate as to which claims may be used under which conditions (i.e. scientific proofs to be submitted etc.).

3. Ethical Claims

The Ministry for Development Co-operation indicated that no legislative initiatives with regard to ethical claims were envisaged for the time being. The Ministry has, therefore, so far not thought about how ethical claims could be defined. As

mentioned above, the Ministry focuses at the moment on pushing the issue of fair trade up the agenda during the next WTO round.

The absence of legislation on ethical claims does not seem to have been the catalyst for any problems in terms of barriers to trade or consumer protection. The authorities, trade associations and consumer associations contacted were unanimous that they had not heard of any problems in this area.

III. VOLUNTARY INSTRUMENTS USED

A. VOLUNTARY INSTRUMENTS IN PLACE

1. Nutritional Claims

No voluntary instruments exist in Germany for nutritional claims.

2. Health Claims

No voluntary instruments exist in Germany for health claims. Nevertheless, for sports foods there exists a position paper from 1993 of the working group on sports foods, which was set up by the Federal Health Office (Bundesgesundheitsamt), and which was composed by eminent scientists from different disciplines.

This position paper has no legal value, but may be used by companies producing sports foods as a reference point. The paper defines sports foods and lays down some compositional standards for sports foods. The paper also contains some indications regarding health claims (Anforderungen an Sportlernahrungen aus der Sicht des Bundesgesundheitsamtes, Stellungnahme der Arbeitsgruppe "Sportlernahrung" im Bundesgesundheitsamt, 8.12.1993, Annex 9).

The paper states that only sportsfoods may use the following three claims:

- "the ingredients of the product equilibrate the loss of energy and/or carbohydrates and/or protein and/or liquid and/or minerals during or after intensive body activity.
- they support an optimum nutritional balance and make the relevant nutrients available, during or after intensive body activity.
- they delay performance decrease during intensive muscular activity." (Anforderungen an Sportlernahrung, point IV. 3))

Furthermore, the German Advertising Council, which is the self-regulatory body of the German advertising industry, has developed guidelines on the advertising of alcoholic beverages. These establish a number of prohibitions in terms of the advertising of alcohol (see below in section C) of this chapter). The functioning of the Advertising Council is explained in more detail further on (see V) B. 2) c))

3. Ethical Claims

a. TransFair

There exist a number of labelling schemes in Germany regarding ethical claims. The German non-profit organisation TransFair is the most well-known actor in this field. TransFair is supported by 39 organisations from the catholic and protestant churches, third world associations to environment associations.

TransFair acts as an independent organisation selling licences for the use of its TransFair-Seal. Over 100 companies have already a licence agreement with TransFair (see TransFair Annual Report 1997, Annex 11).

The seal guarantees that certain social standards are met in third countries (such as minimum salary paid, no child labour, guaranteed workers employment rights according to national and international law). Furthermore, the seal guarantees that certain environmental standards are being respected. The products currently covered by the TransFair-Seal are coffee, chocolate, tea, bananas, honey, orange juice, bonbons.

In terms of labelling, normally the seal is accompanied by a text which states that the product has been fair traded and that fair trade means 'increasing the independence and equality of the disadvantaged partners in the third world', or that fair trade means 'improving the living conditions through guaranteed minimum prices and direct trade relations' (for examples of product labels see Annex No. 12).

b. Fair Traded Flowers

Another labelling scheme which was started at the beginning of 1999 concerns fair traded flowers. An agreement was reached between the trade union 'Bauen-Agra-Umwelt', the aid association 'Brot für die Welt', Terre des Hommes, the human rights organisation FIAN, as well as the flower importing industry 'Verband des deutschen Blumen-, Groß- und Importhandel' and producers in the export countries.

The label guarantees minimum wages, no child labour, equal treatment for all employees, as well as the respect of certain environmental standards. The label states 'from human and environmentally preserving production'.

c. Rugmark

TransFair has since January 1999 also the secretariat of the German Rugmark office. Rugmark is a Foundation based in India and Pakistan, which licences a seal for handknotted rugs, certifying that these rugs have been produced without child labour. Rugmark has created a trademark, which is registered in 14 European countries. So far the Rugmark seal does not make any ethical claim or other ethical statement. But the Rugmark office indicated that they were currently considering eventually adding some information on what the Rugmark seal stands for, which then would also include ethical claims.

B. DEFINITIONS USED IN THE VOLUNTARY INSTRUMENTS

1. Nutritional Claims

No voluntary instruments for nutritional claims exist.

2. Health Claims

No specific definition of claims is used in the position paper on sports foods of the Federal Health Office nor in the guidelines on alcoholic advertising of the German Advertising Council.

3. Ethical Claims

TransFair does not use any definition for ethical claims in its labelling scheme. Nevertheless, in some of the licensing agreements reference is made as to what could constitute a misleading ethical claim. For example, in the licensing agreements for coffee that TransFair concludes with importers, it is made clear that the use of the term "fair traded coffee" may be violating competition laws, if a price is paid to producers which is below the minimum prices set out in the licensing agreement (see TransFair Licensing Agreement for Coffee, Annex 13).

The fair flowers initiative does not use any definition for ethical claims in its labelling scheme.

C. EXISTING PROHIBITIONS, RESTRICTIONS AND EXEMPTIONS

1. Nutritional Claims

No voluntary instruments for nutritional claims exist.

2. Health Claims

The position paper of the Health Office states that claims must be easily understandable, factually correct and scientifically founded. Furthermore, they shall not mislead the consumer or create exaggerated expectations. Finally, claims shall not give the impression that only by eating these products a performance increase is possible (Anforderungen an Sportlernahrung, point IV. 3), Annex 9).

As mentioned above, the guidelines of the German Advertising Council on advertising of alcoholic products, establishes the following prohibitions that (Verhaltensregeln des Deutschen Werberates für die Werbung und das Teleshopping für alkoholische Getränke, article 8/9/10, see Annex 10):

- no statements shall be made which refer to the curing, treatment or prevention of diseases;
- no statements shall be made which attach alcoholic beverages the effect of a medicament;
- no reference shall be made to a medical recommendation or expert opinion; and

- no pictures shall be used of people wearing a uniform of the medical profession or in the process of carrying out an activity of the medical, nursing or pharmacological professions

3. Ethical Claims

In the licensing agreements that TransFair concludes with companies, TransFair sets out the text that companies have to use on the backside of their label (see example of a TransFair Licensing Agreement for Coffee, Annex 13). This text usually contains a number of ethical claims, such as 'improving the living conditions through guaranteed minimum prices and direct trade relations' (see also III. A) 3)).

TransFair indicated that the problems they sometimes encounter with companies arise not so much from the text imposed, but from the length of the text, which is sometimes difficult to put on a package.

D. VOLUNTARY INSTRUMENTS ACCEPTED/RECOGNISED BY THE AUTHORITIES

1. Nutritional

No voluntary instrument on health claims exists.

2. Health Claims

The position paper on sports foods of the Federal Health Office is in general used by the authorities as a guideline.

The guidelines on alcoholic advertising of the Advertising Council are recognised by the authorities, since they implement the relevant provisions on alcoholic advertising of EU Directive 89/552 on TV without Frontiers.

The German Food Industry Association indicated that it had reflected about eventually discussing a code of conduct with consumer groups, but it felt that a code of conduct would not resolve barriers to trade, as German courts would eventually continue their strict application of Directive 79/112.

The main German consumer association (Arbeitsgemeinschaft der Verbraucherverbände) indicated that a code of conduct might be used as an excuse not to legislate.

3. Ethical Claims

The different fair trade labelling schemes mentioned above (see III. A) 3)) are supported by the German Ministry for Development. Most often the ministry provides funding for the local certification structures in the producing countries (see press release of BMZ from 6 May 1999 on the fair traded flower initiative, Annex 14).

Neither the consumer associations, nor industry, nor the authorities felt that there had been any problems in terms of consumer protection or barriers to trade regarding these

fair trade labelling schemes. It was indicated that if there were any consumer protection problems, these could be easily be resolved via the law on unfair competition or via paragraph 17 of the Food Law, which forbids misleading advertising for foodstuffs.

One consumer association, the Consumer Initiative (Die Verbraucherinitiative e.V.), which is also a member of TransFair, indicated that due to the fact that TransFair, Rugmark and other fair trade associations were extremely active, it would be difficult for economic operators to use either misleading or false ethical claims without these coming to the attention of these associations, which would normally immediately become active.

E. OTHER PRACTICES

1. Nutritional Claims

No other practices on nutritional claims have been mentioned to us.

2. Health Claims

The main German consumer association (Arbeitsgemeinschaft der Verbraucherverbände) indicated that there were some more subtle forms of claims, which were either not regulated by law or voluntary instruments and/or which the surveillance authorities did not pursue, as it was not clear whether the legal instruments were sufficient. The consumer association mentioned the case where food companies were apparently sponsoring certain health-related TV series.

The same association also mentioned that there were some claims, which the surveillance authorities seemed to tolerate, but which consumer associations were opposed to. These claims were: "improves the efficiency" and "improves the immune system" (although the later one had been subject to a Court case, see below VI. A) 2)).

The Ministry of Health mentioned that the perception of the surveillance authorities, as to the claims that were making a link to a disease were evolving over time. While several years ago, it would have been impossible to make claims on the cholesterol lowering properties of a product, this seemed now to be generally tolerated by the surveillance authorities.

The Ministry also indicated that one problem, which the law did not address, was the fact that food companies were often using selective statements. The Ministry gave as an example the claim "calcium helps against osteoporosis". While this may be true in itself, it felt that a manufacturer should be obliged to indicate as well that one needed to have an intake of calcium at an early age, in order to help against osteoporosis.

It seems that more subtle forms of health claims, i.e. via sponsoring are not clearly addressed by the law (although it seems possible to act - if necessary - via the Food Law or the law against unfair competition) nor seem to have attracted the attention of the surveillance authorities.

Another issue, which is not clearly addressed by the law are selective health claims, as mentioned above. Such selective statements did in the Ministry's view mask that a balanced diet was necessary.

3. Ethical Claims

TransFair undertook in 1995 a campaign against a TV advertisement by Tchibo, one of the biggest coffee retailers in Germany. The advertisement was for a new coffee called "Privat-Kaffee" and showed happy coffee farmers. TransFair felt that this was romantisicing the real situation of coffee farmers and started a gathering signatures for a petition. In total, 4000 signatures were collected and send to Tchibo (see extract from TransFair Annual Report 1995, Annex 15). Subsequently, Tchibo apparently stopped this TV advertisement.

The example mentioned above by the Consumer Initiative raises the bigger question, in how far images/pictures can constitute a claim. At least in the field of ethical claims, there does not really seem to exist a consumer protection problem in this respect.

IV. VERIFICATION SYSTEMS

A. CRITERIA FOR SUBSTANTIATING CLAIMS

1. Nutritional Claims

The German nutrition labelling decree and the German Food Law do not provide for any criteria for substantiating nutritional claims. Having said that, the nutrition labelling decree establishes the criteria that have to be fulfilled (in terms of energy value of the product etc.) for using certain nutrition claims (see above II. D) 1)).

But the decree does not provide for any documents that a manufacturer would need to submit or keep in his file to proof that he is respecting the composition criteria for being able to make certain nutritional claims. Nevertheless, it is clear that in the case of a lawsuit, a manufacturer should for his own defense keep relevant documentation concerning the production process of the product in question, so as to be able to proof the respect of the composition criteria.

2. Health Claims

Health claims are in general not allowed (see II. D) 2) a)). For the limited list of health claims allowed under the decree on dietary foods, the normal notification procedure for dietary foods as set out under EU Directive 89/398 on foods for particular nutritional uses applies. Under paragraph 4a of the decree on dietary foods (Annex 7) a manufacturer has to notify such a product to the Federal Institute for Consumer Health Protection and Veterinary Medicine (Bundesinstitut für gesundheitlichen Verbraucherschutz und Veterinärmedizin).

For the notification, a manufacturer has to submit a model of the label he wants to use. The Federal Institute then examines whether the product conforms to the criteria

of a dietary food (which are set out in paragraph 1 of the decree and correspond to the criteria of EU Directive 89/398), i.e. whether it is aimed at the consumer group which the manufacturer claims it is destined for, and whether it serves the dietetic purpose claimed by the manufacturer.

Under the decree on dietary foods, the Federal Institute can additionally ask the manufacturer to provide all scientific work and data, which show that the product corresponds to the criteria for a dietary food.

While under this procedure, the Federal Institute examines only whether the product has the dietetic purpose for which it is supposed to be destined, it was clear that the dietetic purpose was often defined by the claim made. The Federal Institute, therefore, also examines the claim made on the label.

The position paper on sports foods of the Federal Health Office states with regard to the criteria for substantiating the specific nutritional claims that may be made on such products: "Each claim has to be […] factually correct and must be scientifically sound" (Anforderungen an Sportlernahrungen, IV. 3, Annex 9). No further criteria are mentioned.

3. Ethical Claims

To be able to use the TransFair seal together with the relevant claims set out in the licensing agreement, an importer has to respect certain criteria. These are in general:

- Buying of products (coffee, bananas, etc.) only from small producers (often contracts list the small producers from which an importer is allowed to buy);
- Providing TransFair access to the invoices, certificates of origin etc. for verification purposes;
- Payment of certain minimum prices (sometimes this provision is in the licensing agreements non-binding); and
- Payment of a certain amount into a social fund.

B. LEGAL/ADMINISTRATIVE SYSTEMS FOR VERIFYING CLAIMS

1. Pre-Clearance Rules/ Guidelines

No pre-clearance rules exist in Germany. Pre-clearance is considered censorship and is, therefore, not applied.

Nevertheless, there exist some informal arrangements, which allow companies to verify their claims. It is almost normal practice for big companies, and companies that have been on the market for a long time, to have informal contacts with their respective surveillance authorities asking them to check the label they want to use. It was clear that this informal verification is not legally binding.

Furthermore, companies often ask independent food chemists, who in Germany give advice as to the lawfulness of a product (in terms of composition and labelling of the product).

The Joint Advertising Office (Gemeinsame Stelle Werbung) of the Working Group of the Regional Media Authorities (Arbeitsgemeinschaft Landesmedienanstalten), which is responsible for the uniform application of the rules concerning advertising and sponsoring on television and radio, indicated that it has from time to time informal contacts with companies who want to get the Office's view on a planned advertising campaign, in order to make sure that their advertising is in line with these rules.

2. Post-Clearance Rules/ Guidelines

a. Civil or criminal law redress procedures

Companies, trade associations, consumer associations and chambers of commerce can start civil redress procedures based on paragraph 1 and paragraph 3 of the law against unfair competition (Annex 8).

Paragraph 1 is a catch-all clause, which states: "Who undertakes actions, which violate good practices, in the framework of commercial activities aimed at competition, can be claimed for injunction and damages". Paragraph 3 is more specific making reference to misleading statements over the commercial conditions, in particular the nature, the origin, the production method or the price determination of products.

For any claims used in private broadcast advertising, the Regional Media Authorities are, in general, responsible. Thus, the Federal Broadcasting Agreement states that for infringements of the agreement the Regional Media Authorities (Landesmedienanstalten) are responsible (Rundfunkstaatsvertrag, paragraph 49 alinea 3, Annex 16). Nevertheless, a special procedure has been set up by the Working Group of the Regional Media Authorities (Arbeitsgemeinschaft der Landesmedienanstalten), which acts as a co-ordinating body of these regional authorities. The Joint Advertising Office (Gemeinsame Stelle Werbung) of the Working Group is charged to look after a uniform application of the relevant advertising rules of the guidelines implementing the Federal Broadcasting Agreement. Members of the Joint Advertising Office are all the Regional Media Authorities, one Authority has the chairmanship (see Verfahrensordnung der Gemeinsamen Stelle Werbung der Landesmedienanstalten, 13. December 1994, Annex 17).

If a Regional Media Authority indicates a violation against the relevant advertising rules, it has to inform the Joint Advertising Office. The Joint Advertising Office then adopts a recommendation by simple majority. The recommendation can be to start an administrative infringement procedure. However, a Regional Media Authority is not obliged to follow the recommendation. In this case, the conference of directors of the Regional Media Authorities is informed of this fact. But the rules do not foresee any possibility to stop a Regional Media Authority for not following a recommendation of the Joint Advertising Office.

The Consumer Protection Association (Verbraucherschutzverein e.V.), based in Berlin, has in its statutes the specific mandate to stop unlawful competition (see Annex 18). Its members are all regional consumer associations, as well as the main federal consumer association (Arbeitsgemeinschaft der Verbraucherverbände). It is, therefore, extremely active in asking companies under the law on unfair competition

to make declarations of forbearance, whereby the company declares vis-à-vis the association that it will no longer make the admonished claim/advertising. If the company does not make such a declaration, the Consumer Protection Association brings the complaint to court.

b. Specific procedures for claims

The authorities have the possibility to follow a specific procedure for nutrition and health claims under the German Food Law. As set out in paragraph 41 of the Food Law (Annex 2), the food and medicine surveillance authorities in the German regions are responsible for supervising compliance with the Food Law. The food and medicine surveillance authorities have around 5000 employees (figure indicated by the Ministry of Health).

The food and medicine surveillance authorities are notably allowed to take samples (paragraph 42 of the Food Law).

Based on the Law on Disciplinary Fines (Gesetz über Ordnungswidkrigkeiten, BGBl. I 1968, S. 481) the surveillance authorities can impose certain civil charges against companies not respecting labelling rules (for the fines applicable see V. E)). Based on the Food Law the surveillance authorities can in some cases bring a criminal charge against companies (for these cases see V. E)).

No specific procedures exist for ethical claims.

c. Out-of-court procedures

The German law against unfair competition allows the establishment of settlement points (Eingigungsstellen) within the chambers of commerce (RGBl. 1909, S.499, last amended in 1998, paragraph 27 following, Annex 8). Such settlement points exist in all German regions.

Under the law against unfair competition, consumer associations, trade associations, and companies are allowed to bring complaints to these settlement points. The Centre for Fight against Unlawful Competition (Zentrale zur Bekämpfung unlauteren Wettbewerbs) has a special role: it is a private association with around 1600 members, mostly companies, trade associations and chambers of commerce. It acts mainly on the basis of the law against unfair competition and brings every year thousands of cases in front of these centres (see Annex 19).

The procedure that the Centre follows is the following:

- Complaints are sent to the Centre, mostly by its members, but complaints also come sometimes from consumers.
- If after examination the Centre comes to the conclusion that a company is in violation of the law on unfair competition (and notably with regard to claims and advertising), it asks the company to make a declaration of forbearance, whereby the company declares vis-à-vis the Centre that it will no longer make the admonished claim/advertising and will pay a small financial penalty.

- If the company indicates that in its view it did not violate the law on unfair competition, there are two possibilities. If the company agrees, it is possible to refer the matter to the settlements points at the chambers of commerce. If the company opposes to go to the settlement point, the issue is brought by the Centre to the courts.
- If the company agrees to go to a settlement point, the settlement point makes a proposal as to how to settle the issue. The settlement points cannot take legally binding decisions. If the proposal of the settlement point is accepted by the Centre and the company in question, the procedure ends there. If not, it is referred to court.

The settlement points are usually composed of a chairman, who has to have the qualification of a judge, and two businessmen. These settlement points work in general quite well, but suffer sometimes from time delays, as the members of the settlement points are working on a voluntary basis.

Another out-of-court complaint procedure is provided by the German Advertising Council (Deutscher Werberat), which is the self-regulatory body of the German advertising industry. The Advertising Council is composed of 12 members regrouping those that advertise, those that produce advertising, and advertising agencies (for more details see Arbeitsgrundsätze des deutschen Werberates). The Advertising Council accepts only complaints from consumers. If companies complain against a competitor, the Advertising Council asks the company to exercise its rights himself (see Verfahrensordnung des Deutschen Werberates, article 2, Annex 20), i.e. to enter into contact with the competitor and eventually bring the competitor to the courts.

The Advertising Council is responsible for advertising, which is questioned by the consumers to be immoral, unethical, sexist etc. When the Advertising Council considers that a certain advertising violates German law and notably the law on unfair competition, it refers the matter to the Centre for Fight against Unlawful Competition (see Verfahrensordnung des Deutschen Werberates, article 2, Annex 20). The Advertising Council indicated that consumers often do not know about the Centre and, therefore, a number of consumer complaints are first addressed to the Council, although they are a matter for the Centre.

Complaints which address a violation of the medicine advertising law are referred to the Association for Fair Medicament Advertising (Verein für lautere Heilmittelwerbung).

Sometimes, the Centre refers complaints back to the Advertising Council, where it considers that the advertising does not violate German law. In this case, the Advertising Council considers the matter further to see if it shall become active.

In some few cases, the procedure of the Advertising Council may overlap with the one of the Centre. Due to the fact that the Advertising Council has a specific guideline on alcohol advertising, which makes reference to health claims with regard to alcoholic products, we explain hereunder the procedure of a complaint under the procedure of the Advertising Council (Arbeitsgrundsätze des Deutschen Werberates, article 3 following, Annex 21):

- Complaints have in general to be submitted in written form. The confidentiality of the complainant is ensured.
- If the Advertising Council considers itself to be competent, and it considers the complaint not to be evidently ungrounded, it will ask the advertiser or the advertising agency to comment on the complaint within a certain deadline.
- The advertiser or the advertising agency can indicate that it will change the advertisement or no longer run the advertisement.
- In case that the advertiser or the advertising agency do not comment or indicate that they consider the complaint to be ungrounded, the Advertising Council takes a decision. Decisions are taken by simple majority.
- The Advertising Council may decide that the complaint is indeed ungrounded.
- The Advertising Council may also decide to ask the advertiser or the advertising agency to modify or stop the advertisement and to inform the Advertising Council within a certain deadline if it has done so.
- If the advertiser or the advertising agency decides not to change or stop its advertising or does not inform the Advertising Council whether it has done so, the Advertising Council can make his decision public.

The system works in general quite well and efficiently. A recent example of a health claim that the Advertising Council admonished concerned an alcoholic beverage, which was sold with the following claim: "Did you know that beer increases the performance?" To this statement was added that a certain doctor from a medical institute in Rome had done tests, which had shown that the performance of sportsmen drinking one liter of beer per day was higher than the performance of sportsmen who drank less beer. The Advertising Council admonished the advertisement, as it was against its guideline on the advertising of alcoholic products, which forbids making reference to medical recommendation (see Spruchpraxis Deutscher Werberat, Bonn 1997, page 17, Annex 22).

No out-of-court procedures exist for ethical claims.

C. LEGAL PERSONS ENTITLED TO TAKE LEGAL ACTION

Under the unfair competition act, only companies, trade associations, consumer associations and chambers of commerce can start civil redress procedures (paragraph 13).

For individual consumers, it is not possible to bring a complaint to the courts regarding misleading/unlawful claims. But consumers can complain to the Centre for Fight against Unlawful Competition, as well as the German Advertising Council and any consumer association. These will then verify in how far the claim is valid and can then undertake action (see above point B).

D. BURDEN OF PROOF

The burden of proof lies with the complainant under the law on unfair competition, as well as the Food Law. Nevertheless, the German Food Law Association (Bund für Lebensmittelrecht und Lebensmittelkunde) indicated that in its view it was in practice the companies who would be trying to justify that their claims were scientifically

proven, i.e. the burden of proof was therefore in practice already with the companies making claims.

Furthermore, the Federal Court (Bundesgerichtshof) concluded in several judgements that the burden of proof was with the defendant where he was using an opinion which is controversial amongst experts and without also mentioning the dissenting scientific view (see also below VI. A) 2.).

Nevertheless, consumer associations seem to experience particular problems with regard to the burden of proof in case of misleading claims (see below F) 2)).

E. APPLICABLE PENALTIES

Under the German Food Law, the penalties vary depending on whether it is an infringement against paragraph 17 on misleading marketing and advertising or paragraph 18 on health related marketing and advertising (see above II. A) 2)).

An infringement against paragraph 17 is considered a criminal offence (Straftat) and can be punished with imprisonment of up to one year or a fine (see Food Law paragraph 52 alinea 1 point 10, Annex 2).

An infringement against paragraph 18 is considered an infringement (Ordnungswidrigkeit) and can be punished with a fine of up to 50,000 Deutschmarks (= 25,000 Euro) (see Food Law paragraph 53 alinea 2 point 1. 3), Annex 2).

It is interesting to note that while the dietary order lists a number of penalties applying, no reference is made to the penalties applying for those who do not respect the allowed health claims listed in the dietary order (paragraph 3). The Ministry of Health explained that in this case the penalties as defined under the Food Law for misleading and forbidden claims would apply (for these penalties see paragraphs above in this chapter).

Under the unfair competition act the penalties applying are listed in the civil court order (Zivilprozeßordnung, BGBl. I 1950, S. 535, last amended in 1997). Under paragraph 890 of the order, a Court can ask the party responsible not to undertake certain actions again (e.g. using a certain claim). In case the party responsible does not respect the Court's ruling, a financial penalty of up to 500.000 Deutschmarks (250.000 Euro) can be imposed. Where it is not possible to obtain from the party responsible, this amount of money, imprisonment up to 6 months can be imposed.

F. COMMENTS APPLICABLE TO HEALTH CLAIMS

The Ministry of Health indicated that as the surveillance of food and pharmaceutical products was organised on a regional basis in Germany, this sometimes led to the situation whereby one surveillance authority in one region may allow a claim, while an authority in another region, may forbid the same claim.

In order to avoid barriers to trade within Germany, the surveillance authorities have established a number of bodies to deal with such problems. Thus, there is every year several meetings of the Working Group of Food Chemists (Arbeitskreis

Lebensmittelchemischer Sachverständiger) and the Working Group of the Chief Medical Officials of the Regional Surveillance Authorities (Arbeitskreis der Leitenden Medizinalbeamten der Überwachungsbehörden der Länder). The latter has a working group on labelling.

Barriers to trade within Germany may, therefore, sometimes come up, but only during a limited period of time, until the surveillance authorities have found an agreement. The German Food Industry Association indicated that in practice these problems were minimal. The Food Industry Association felt that a far bigger problem in terms of barriers to trade was the very narrow interpretation of the Food Law with regard to health claims by the surveillance authorities.

In terms of consumer protection, the main German consumer association (Arbeitsgemeinschaft der Verbraucherverbände) and the Ministry of Health concurred that the internet was posing a problem, as it was difficult to undertake procedures against claims used on internet sites, specifically where the advertising was provided through servers outside of the EU. The consumer association was in favour of the country of destination principle with regard to Internet advertising.

In its answer of October 1996 to a Commission request for information on miracle products, the German Government indicated that the surveillance instruments available, may be less efficient with regard to door to door selling and sale by mail.

Similar, the Consumer Protection Association (Verbraucherschutzverein) indicated that there existed sometimes problems in enforcing declarations of forebearance and court rulings in the case of foreign companies selling products in Germany. It felt that possibilities for consumer associations to become active in other EU countries should be improved.

As to the burden of proof, the main German consumer association stated that it favoured a change of the burden of proof. Consumer associations had often problems with claims that could not be scientifically proven. It was difficult for consumer associations to find and finance an expert who could provide an opinion proving that the claim could not be scientifically proven. Therefore, many cases were not brought to court. The Consumer Protection Association indicated that this was in particular the case for misleading health claims. Courts often dismissed a complaint, where the association was not able to have sufficient scientific material that showed that the claim made was misleading.

On the question of pre-clearance or post-clearance of claims, the Consumer Protection Association indicated that it had not yet established a position. But the representative of the Consumer Protection Association who we interviewed felt, on a personal basis, that pre-clearance via an administrative body or agency would only create unnecessary bureaucracy. Such pre-clearance could eventually be considered censorship. He felt that the law against unfair competition was a strong enough instrument, which would make the introduction of a pre-clearance system unnecessary.

The German food industry association felt that pre-clearance was not necessary if rules were in place that would allow an easy a posteriori verification. Therefore,

companies should have all scientific documentation at hand when making a claim. The association indicated that such a pre-clearance would slow down the putting on the market of a product, which meant reducing competitiveness. Furthermore, such a pre-clearance system would eventually need a large bureaucracy function.

V. CASE LAW

1. Nutritional Claims

Little case law in Germany on nutritional claims exists. The High Court of Cologne (Oberlandesgericht Köln) rules in 1994 on the use of the term "poor in natrium" on mineral water (6 U 32/94, OLG Köln, 30/9/94, Annex 23).

A complaint was put forward by a consumer protection association against a producer who was using the term "poor in natrium" on his natural mineral water, which contained 112mg/l of natrium. The Court found that this was a misleading claim based on paragraph 3 of the law against unfair competition and an Annex to the decree on mineral water.

The Court stated that using the term "poor in natrium" was a similar indication as "suitable for a diet poor in natrium", which under the decree on mineral water has to contain less than 20mg/l of natrium.

The Court also concluded that this statement was not only misleading but it also constituted unfair competition, as it would influence consumers - who follow a diet poor in natrium - to turn towards this product. Competitors selling an identical product but without such an indication would therefore suffer from unfair competition.

The Court ruled that the company could no longer use the term "poor in natrium" for its natural mineral water and was asked to cover the costs of the consumer protection agency for bringing the complaint to the Court (costs of 267,50 DM).

The Court does not give any definition for nutritional claims, but uses without prejudice a number of terms to describe the claim "poor in natrium". These are: reference (Hinweis), designation (Bezeichung), term (Begriff), label (Kennzeichung).

2. Health Claims

There are a significant number of cases in Germany on health claims. One of the most recent cases that were considered by the Federal Court (Bundesgerichtshof) concerned a complaint brought forward by a trade association against a company distributing a food supplement which used the following claim (I ZR 125/95, BGH, 4/12/97, Annex 23):

"If sometimes the joints crack and creak, it could be that you are missing 'lubricating oil for joints' and that wear and tear is coming to the forefront…In many such cases gelatine-hydrolysat has proved successful".

The Federal Court agreed with the lower courts that this was against paragraph 18 of the Food Law, which in alinea 1(1) forbids the use of statements referring to the elimination, alleviation or prevention of sickness. Furthermore, it was against paragraph 1 of the law on unfair competition and constituted unfair competition.

The Federal Court elaborated that even if a reference is not explicitly made clear to a certain illness, it was sufficient to use a clear paraphrase of an illness, or where the symptoms described made a clear reference to a specific sickness. In this case, the Court held that the claim used clearly made reference to arthritis.

The Court also gave an explanation why under German Food Law disease related claims are forbidden. This is mainly for two reasons: - to avoid the danger of self-medication and to avoid that consumers might believe that foodstuffs have the same effects as medicines.

The problem of indirect references to a disease has also been considered in a number of other cases. The High Court Hamburg (Oberlandesgericht Hamburg) ruled in 1994 against a company selling food supplements using the claim "improves the immune system" (3 U 23/94, OLG Hamburg, 5/5/94, Annex 23). The Court stated that paragraph 18, alinea 1 (1) forbids statements on the prevention, curing or treatment of diseases. But this also covered indirect statements on the prevention, curing or treatment of diseases. The Court concluded that the consumer would interpret the claim "improves the immune system" not as improving health, which the Court indicated was allowed under the Food Law. Instead the Court concluded that this claim would be interpreted by the consumer as making reference to prevention of infections, notably flues. The Court ruled that the claim "improves the immune system" was unlawful under paragraph 18, alinea 1 (1) of the Food Law and confirmed the ruling of a lower court for the continuation of the injunction.

The word 'claim' has not been further defined by the Court, which uses the terms 'advertising' and 'claims' without distinction to describe it.

Similarly, the State Court of Hamburg (Landesgericht Hamburg) ruled against a producer of cough-drops using the claims: "In particular in case of weather provoking colds you should protect your respiratory ducts in a prophylactic manner"; "Thyme helps in particular in the case of spasmodic cough"; "Fennel loosens and alleviates in case of cough". The Court concluded that this was against paragraph 18, alinea 1 (1) of the Food Law and paragraph 1 of the law on unfair competition (15 O 643/77, LG Hamburg, 25/1/78, Annex 23).

The Court concluded that while a simple throat irritation, or a throat that is overstrained during a short period of time cannot be considered a disease or a disease symptom, which in the Court's view also falls under the prohibition of paragraph 18, alinea 1 (1) of the Food Law. Nevertheless, the claims used suggest that these cough-drops help curing or at least alleviate strong forms of coughs, i.e. spasmodic coughs, which have to be considered a disease, as they "impair in an intensive and enduring way the general condition".

These claims are not further defined by the Court, which simply call them 'effect statements' (Wirkungsaussagen). The Court also gave an explanation why under

German Food Law disease related claims are forbidden: - to avoid the danger of self-medication and to avoid that consumers might believe that foodstuffs have the same effects as medicines.

Another example of indirect references to diseases has been considered by the State Court of Oldenbourg (Landgericht Oldenburg). It ruled against an egg producer, who was selling his eggs with the claims: "The egg for all who follow a cholesterol conscious nutrition"; "The first cholesterol-neutral egg: Naturally rich in unsaturated fatty acids, which counteract an increase of the cholesterol level". The Court concluded that the average consumer would make a link between the cholesterol level and heart and circulation diseases (11 O 138/96, LG Oldenburg, 22/8/96, Annex 23). This was against paragraph 18, alinea 1 (1) of the Food Law and paragraph 1 of the law against unfair competition. The egg producer was asked not to use these claims any more.

These claims are not further defined by the Court, which simply calls them "diseases related advertising".

An interesting case, which describes in further detail the difference between a health related claim that is allowed under German food law and a disease related claim which is forbidden, was decided in 1992 by the Chamber Court of Berlin (Kammergericht Berlin).

The Court had to rule on the sale of a vitamin supplement, which was using the claim "…protects against fat soluble antioxidants…the so called free radicals, which attack the cells", "it stabilizes the walls of the cell… and can therefore reduce the damaging effects of the free radicals". The Court concluded that this was a disease related claim, as stabilizing the walls of the cell meant preventing a disease, i.e. preventing the damaging of the cells (27 U 6020/92, KG Berlin, 14/12/92, Annex 23).

The Court gave a number of examples of the difference between a health-related claim and a disease-related claim. A health-related claim was in the Court's view a claim that made reference to the maintenance or improvement of the health via a foodstuff, e.g. "eat more apples and you keep healthy", or "bread X for a healthy nutrition". On the other hand, whenever reference was made to a disease, it was a disease-related claim and was, therefore, forbidden. The Court gave the following example: "disease is serious - bread X for a healthy nutrition".

Another interesting case concerns the sale of bed-linen under the name 'Rheumalind', which in English could be best translated as 'Rheumatism Relief'. A competitor complained that using this term was unfair competition under the law on unfair competition, as bed-linen containing pure lamb wool did not have the effect of alleviating rheumatism (I ZR 127/89, BGH, 7/3/91, Annex 23). The main point of the complaint concerned the burden of proof. In its ruling, the Federal Court concluded that in general the burden of proof was with the plaintiff. But - as the Court held in several cases - the burden of proof is on the shoulders of the defendant where he uses an opinion which is controversial amongst experts, and without also mentioning the dissenting scientific view.

In the case at hand, the Federal Court concluded that further examination by experts was needed in order to clarify whether bed-linen containing pure lamb wool could alleviate rheumatism or not. As the product in question is neither a foodstuff, nor a medicine, the only legislation that applies is the law on unfair competition.

3. Ethical Claims

There basically exists no case law on ethical claims. The only case we came across concerns a ruling on a cosmetic product using the claim "product not tested on animals". The complaint was brought forward by the Centre for Fight against Unlawful Competition against a producer of cosmetic products (KfH 0 39/96, LG Mosbach, 1/10/96, Annex 23).

The Regional Court of Mosbach (Landgericht Mosbach) concluded that the claim "product not tested on animals" was a breach of the law against unlawful competition. The Court concluded that as all similar cosmetic products of the competitors had not been tested on animals, this claim was clearly unlawful competition. The Court stated that the average consumer could consider the product in question had been produced in "a way respecting humanitarian and ecological requirements", which those of the competition did not. Also, consumers may be prepared to pay more money for such a product, although all similar products of the competitors fulfilled the same quality requirements.

B. REMARKS ABOUT BARRIERS TO TRADE AND LACK OF CONSUMER PROTECTION

1. Nutritional Claims

With regard to nutritional claims, German case law does not indicate any relevant consumer protection problems and/or barriers to trade.

2. Health Claims

The German food industry indicated that it was problematic that German courts were interpreting the ban on disease related claims in such a restrictive way. It felt that if one was pursuing the courts' logic far enough even claims that were referring clearly to health and not to a disease may be forbidden. It considered that forbidding a claim such as "improves the immune system" was already reaching this borderline. It was, therefore, difficult for the industry to make claims, which could contribute to consumers' health.

The Advertising Council felt that it was problematic that German courts were following a different consumer concept than the European Court of Justice. While the European Court of Justice was basing its rulings on the concept of the informed consumer, German courts were basing their rulings on the concept of the average consumer, who may not be well informed. This could potentially lead to barriers to trade.

On the other hand, the main German consumer association (Arbeitsgemeinschaft der Verbraucherverbände), as well as the Consumer Protection Association

(Verbraucherschutzverein) concurred that it was difficult for consumer associations to find an expert (and pay an expert) who could provide an opinion proving that the claim could not be scientifically proven. Courts often dismissed a complaint, where the consumer associations were not able to have sufficient scientific material that showed that the claim made was misleading.

3. Ethical Claims

Apart from the case cited above, no problems seem to exist in terms of consumer protection and/or barriers to trade.

VI. MEANS OF COMMUNICATION

With regard to nutritional and health claims, the German Food Law applies in the interpretation of the Ministry of Health to all means of communication. Thus paragraph 17 and 18 of the Food Law make reference to the marketing and advertising of food products.

The law on unfair competition (Annex 8), which applies to any misleading claim covers equally all means of communication. It states in paragraph 1 and 3 that it applies to 'commercial activities' (geschäftlichen Verkehr). The Ministry of Health, as well as the Centre for Fight against Unlawful Competition confirmed that in its view the unfair competition act applies to all means of communication.

The Federal Broadcasting Agreement (Rundfunkstaatsvertrag, Annex 16) which regulates television and radio broadcasting makes clear that misleading advertising is forbidden (Rundfunkstaatsvertrag, paragraph 7 alinea 1). The guidelines developed by the Regional Media Authorities (Arbeitsgemeinschaft Landesmedienanstalten), which is responsible for administering the Agreement state in reference to this provision that the specific legislation applying for advertising, consumer protection and unfair competition apply. The guidelines make particular reference to the Food Law (Gemeinsame Richtlinien der Landesmedienanstalten für die Werbung, zur Durchführung der Trennung von Werbung und Programm und für das Sponsoring im Fernsehen, 16. Dezember 1997, paragraph 3 alinea 2; and Gemeinsame Richtlinien der Landesmedienanstalten für die Werbung, zur Durchführung der Trennung von Werbung und Programm und für das Sponsoring im Hörfunk, 16. Dezember 1997, paragraph 3 alinea 2, Annex 24).

VII. STATISTICS ON CLAIMS

It has proven extremely difficult to obtain statistical information on claims. One of the best sources proved to be the Centre for Fight against Unlawful Competition. The Centre received in 1998 a total of 21.190 complaints relating to unlawful competition (see Zentrale zur Bekämpfung Unlauteren Wettbewerbs e.V. Frankfurt am Main, Rückblick auf die Arbeit im Jahre 1998, p. 1, Annex 25). Out of these, the Centre estimates that around 1300 complaints concerned health and disease related advertising. More specifically concerning food-related claims, the Centre estimates that around 100 complaints are received each year, of which only 3 concern

complaints on nutritional claims. The rest concern health claims. Most of these complaints were settled out-of-court.

Another very useful source proved to be the Consumer Protection Association in Berlin. It has a data base that goes back to 1992 and tracks all the letters it has sent to companies asking for declarations for forbearance. The Consumer Protection Association indicated that its database contains around 150 such admonitions covering health related advertising, of which 80 concern advertising for slimming product.

The German Consumer Association (Arbeitsgemeinschaft der Verbraucherverbände) reckons that each year several hundred complaints are received by all the consumer associations in Germany regarding health/medical claims.

The German Advertising Council also has some statistics regarding complaints that are being submitted. In 1997, the number of complaints received concerning foodstuff advertising was 23. But this number went down to 8 in 1998. The statistics, unfortunately, do not reveal how far these claims concerned health claims or other sorts of food advertising related complaints. The number of complaints regarding alcoholic advertisements numbered at 19 in 1998 (see Jahrbuch Deutscher Werberat 1999, 25-26, Annex 26).

VIII. ANNEXES

1) Verordnung zur Neuordnung der Nährwertkennzeichnungsvorschriften für Lebensmittel, BGBl. I 1994, S. 3256
2) Lebensmittel- und Bedarfsgegenständegesetz, BGBl. I 1997, S. 2296
3) Verführerische Werbung für probiotische Milchprodukte, Gesundheitsfördernder Effekt nicht nachgewiesen, in: Arbeitsgemeinschaft der Verbraucherverbände, Verbraucherpolitische Korrespondenz, Nummer 9, 27/4/99
4) Materials from Press Conference of the Bund für Lebensmittelrecht und Lebensmittelkunde e.V., 6/5/1999
5) Verordnung über natürliches Mineralwasser, Quellwasser und Tafelwasser, BGBl. I 1984, S. 1036
6) Verordnung über Milcherzeugnisse, BGBl. I 1970, S. 1150
7) Verordnung über diätetische Lebensmittel, BGBl. 1988, S. 1713, as last amended in 1994
8) Gesetz gegen den unlauteren Wettbewerb, RGBl. 1909, S. 499 as last amended in 1998
9) Anforderungen an Sportlernahrungen aus der Sicht des Bundesgesundheitsamtes. Stellungnahme der Arbeitsgruppe "Sportlernahrung" im Bundesgesundheitsamt, 8/12/1993
10) Verhaltensregeln des Deutschen Werberats über die Werbung und das Teleshopping für alkoholische Getränke, Fassung von 1988
11) TransFair: Jahresbericht 1997
12) FairTrade labelling examples using the TransFair Seal
13) Sample of Lizenzvertrag Kaffee TransFair
14) Pressemitteilung des Bundesministerium für wirtschaftliche Zusammenarbeit vom 6/5/1999 zur Fairen Blumen Initiative

15) TransFair: Jahresbericht 1995, p. 17
16) Staatsvertrag über den Rundfunk im vereinten Deutschland
17) Verfahrensordnung der Gemeinsamen Stelle Werbung der Landesmedienanstalten, 13/12/1994
18) Auszug aus der neuverfassten Satzung des Verbraucherschutzverein e.V.. Verabschiedet auf der Mitgliederversammlung vom 10/6/1994
19) Kurzübersicht über Zentrale zur Bekämpfung Unlauteren Wettbewerbts e.V.
20) Verfahrensordnung des Deutschen Werberats, Fassung vom 24/9/1979
21) Arbeitsgrundsätze des Deutschen Werberatss, Fassung von 1979
22) Spruchpraxis Deutscher Weberat, Bonn 1997, section alcoholic beverages
23) Court Cases:
- 6 U 32/94, OLG Köln, 30/9/94
- I ZR 125/95, BGH, 4/12/97
- 3 U 23/94, OLG Hamburg, 5/5/94
- 15 O 643/77, LG Hamburg, 25/1/78
- 11 O 138/96, LG Oldenburg, 22/8/96
- 27 U 6020/92, KG Berlin, 14/12/92
- I ZR 127/89, BGH, 7/3/91
- KfH 0 39/96, LG Mosbach, 1/10/96

24) Gemeinsame Richtlinien der Landesmedienanstalten für die Werbung, zur Durchführung der Trennung von Werbung und Programm und für das Sponsoring im Fernsehen, 16/12/97; Gemeinsame Richtlinien der Landesmedienanstalten für die Werbung, zur Durchführung der Trennung von Werbung und Programm und für das Sponsoring im Hörfunk, 16/12/97
25) Zentrale zur Bekämpfung unlauteren Wettbewerbs e.V., Rückblick auf die Arbeit im Jahre 1998
26) Jahrbuch Deutscher Werberat 1999, page 25-26

IX. DATABASE OF CONTACTS

H. GREECE

I. EXECUTIVE ANALYSIS

A. INTRODUCTION

Overall, the issue of claims, be it nutritional, health or ethical, is not a priority issue for stakeholders, nor is it particularly recognised as a problem. However, following the recent "Belgium dioxin crisis", the Greek authorities have realised the urgent need to establish a uniform control body to tackle all issues pertaining to the food & drink industry.

The Consumer General Secretariat of the Ministry of Development is responsible for setting-up the first Uniform Foodstuffs Control Board in Greece. The Board, soon to come into effect, will only deal with packaged foodstuffs and will be assisted by a number of consumer organisations, industry representatives, as well as the National Pharmaceutical Organisation and the State Laboratory for General Chemistry. The Control Board will serve as a starting point so that the issue of claims is more closely monitored by the State and consequently dealt with via clearly defined administrative channels.

B. MEMBER STATES POLICY

1. Nutritional Claims

The definition provided by the Greek legislation on 'Nutritional Claims' conforms to the EU definition in all respects. According to Ministerial Decision no. 843/91 FEK 80, Article 11a, par. 2b a nutritional claim is defined as “Any representation and any advertising which states, implies or leads to the conclusion that a food has particular nutritional properties according to the energy (calorific value)”.

2. Health Claims

A definition for 'Health Claims' is not provided as such by Greek legislation. However, health claims are considered as anything making reference to health in general. It should be mentioned that the National Food & Drink Code of Conduct provides the notion of health claims in terms of prohibitions. Article 11 refers to Article 2 of 709/112: labelling and the way it is presented should not "attribute to a foodstuff properties of prevention, treatment or cure of diseases or insinuate such properties, with the reservation of the special provisions provided for natural mineral waters and foodstuffs for particular nutritional uses.

3. Ethical Claims

No definition of an 'Ethical Claim' is provided in Greek legislation. The assumption is that they would fall under the misleading advertising Directive implementing rules.

C. VOLUNTARY CODES OF PRACTICE

The Hellenic Advertising Agencies Association has issued a Code of Conduct, which is binding for all its members as well as the media. It makes reference to misleading

advertising and indirectly to claims. The Federation of Hellenic Food Industries (SEVT) conforms to all rules and regulations. The Code is accepted and recognised by the Greek authorities as the official self-regulatory document dealing with the control of advertisements.

D. VERIFICATION SYSTEMS

The National Food & Drink Code of Conduct and other relevant legislative documents do not provide any criteria for substantiating claims in particular. Specifically, there is no list of documents mentioned in relevant Greek legislation (except baby foods) to determine the necessary proof that needs to be adduced in order to substantiate a claim made on a foodstuff. On the other hand, it is considered inherent that the manufacturer who wishes to use a certain claim is in a position to defend this with scientific documentation.

A formal system and/or organisation responsible for the control of foodstuffs and claims does not exist in Greece. Relevant controls fall under the competence of various public organisations such as the Ministry of Development (State Market Inspection Service), the State Laboratory of General Chemistry and the National Pharmaceutical Organisation. There is an evident overlap of responsibility between all the above mentioned organisations, especially between the State Laboratory for General Chemistry and the National Pharmaceutical Organisation, which in the view of consumers leads to a lack of clear control.

No pre-clearance rules exist in Greece officially. As to post clearance, a consumer wishing to sue for a misleading claim is obliged to do so through a consumer organisation. Such cases are submitted to the civil courts and are most often handled through the procedure of provisional measures.

According to Unfair Competition Law and Consumer Protection Law, it is not clear with whom lies the burden of proof. Evidently, Greek legislation does not define whether the producer/manufacturer or the consumer organisation has the ultimate responsibility to prove that a claim is misleading or not. However, the authorities indicated that the burden of proof lies in practice with both parties.

E. MEANS OF COMMUNICATIONS

On a theoretical basis, all legislative documents - related to nutritional or health claims - are applicable to all means of communication. However, there is a possible discrepancy between law and practice based on two facts. First, the absence of a relevant body for the control of claims (both nutritional and health) and second, the very wide spectrum of activities - apart from the verification of claims - of the organisations currently responsible for this issue, such as the State Laboratory for General Chemistry and the National Pharmaceutical Organisation. Consequently, there could be differences as to the strictness and intensity with which the law is applied among the various means of communication.

F. CONSUMER PROTECTION

From the viewpoint of consumer organisations, the issue of claims is inefficiently approached by the State. At the same time, lack of knowledge on their behalf has prevented them from thoroughly informing consumers on the possible issues. The limited resources of the Greek

State as well as the fact that they admit that the control systems in place for claims need improvement and that certain sections of the Greek legislation relating to Food & Drink issues are outdated clearly demonstrates an apparent lack of consumer protection. According to the consumer organisations' viewpoint, consumer rights are not effectively protected and the action taken by the former is becoming somewhat restricted. This occurs due to the fact that the control system is complicated and there are many overlaps of responsibility between the various competent bodies.

G. BARRIERS TO TRADE

There are no apparent problems.

H. CASE LAW

There is no body of case law, although there are two cases, which found both claims to be misleading, resulting in the closure of one company and the withdrawing of the claim on the packaging in the other.

I. STAKEHOLDER ANALYSIS

1. Government Authorities

- Public sector representatives expressed the wish to see all issues relating to claims being regulated at EU level. It is their belief that detailed EU rules that could serve as a sanction would help Member States define the relevant boundaries on claims and harmonise their legislation in an appropriate way, which does not leave any grey areas unresolved.

- However, it was also suggested that further regulation should avoid being 'suffocating'. This should occur in a way so as to literally protect consumers instead of confusing them with the variety of claims that may appear on the market. On the other hand, the industry's concerns should also be accounted for, as additional limitations imposed on foodstuff may in practice constitute a barrier to trade.

2. Consumer Organisations

- They wish to see further protection through updated national and ideally EU level rules as well as clear responsibilities as to who in Greece verifies claims. Their relative inexperience on the issue of claims prevented them from having a more detailed viewpoint, although they were of the opinion that a lack of consumer protection existed.

3. Industry

- The industry in general is in favour of EU action, supporting the CIAA Code as the way forward.

- The Hellenic Advertising Agencies Association, are against further regulation of claims and their incorporation in the EU Directive on Misleading Advertising. It is their belief that this would be highly dysfunctional and would ultimately lead to barriers to trade. Therefore, their suggestion is that self-regulation would be the best solution. If the law

becomes more specific and strict on claims, it may restrict the food and drink industry that use more technologically advanced methods than others for the improvement of their products.

* * *

II. MEMBER STATE POLICY

A. DEFINITION OF CLAIMS

1. Nutritional Claims

According to Ministerial Decision no. 843/91 FEK 80 of 19/11/1991 Article 11a, par. 2b (see Annex 1) a nutritional claim is defined as:

> "Any representation and any advertising which states, implies or leads to the conclusion that a food has particular nutritional properties according to the energy (calorific value):
>
> * Provides,
> * Provides at a reduced or increased rate or does not provide
> Or also according to the nutritional substances it:
> * Contains,
> * Contains at a reduced or increased rate, or
> * Does not contain".

Nevertheless, a quantitative or qualitative statement for particular nutritional substances does not constitute a 'nutritional' claim, if such a statement is requested by the Code.

Article 10, par. 3 of the National Food & Drink Code of Conduct (see Annex 2) provides for a definition of what is a misleading claim: it is "forbidden as it aims at misleading the consumers, and is persecuted as misleading any statement or advertising, in any way, of a foodstuff, with which it is directly or indirectly implied that the food offered for consumption by a particular producer, is particularly rich (or in some cases poor) in one or more of its basic nutrient ingredients, or that it contains these (ingredients) in higher, or in some cases lower, ratios than usual, even if this is real, if these ingredients are included in a percentage that lies within the agreed limits, determined by the Code, for the corresponding type of food."

As such, a misleading claim is also considered as any writing on the packaging regarding a foodstuff's content of a certain ingredient, at a spot clear and distant from the one, where the food's composition is provided.

The definition provided by the Greek legislation on 'Nutritional Claims' conforms to the EU definition in all respects.

However, the Greek definition and the definition given by the Codex Alimentarius differ in terms of specificity. For example, the distinction between the four categories of nutritional claims (nutrient content claims, comparative claims, nutrient function claims and claims related to dietary guidelines or healthy diets), given by the *Codex Alimentarius*, is not included in the definition provided by the Greek legislation.

2. Health Claims

A definition for 'Health Claims' is not provided as such by Greek legislation. However, health claims in Greece are considered as anything making reference to health in general. It

should be mentioned that the National Food & Drink Code of Conduct provides the notion of health claims in terms of prohibitions (Article 11, par. 2.a.ii & Article 10, par.2). The definition of what is a misleading claim as stated in Article 11, par. 2.a.ii (see Annex 3) of the National Food & Drink Code of Conduct, could be interpreted as a negatively defined health claim, i.e. in terms of prohibitions.

According to Article 11, par. 2a.ii:

The labelling and the way it is presented should not "attribute to a foodstuff properties of prevention, treatment or cure of diseases or insinuate such properties, with the reservation of the special provisions provided for natural mineral waters and foodstuffs for particular nutritional uses".

Article 10, par.2. of the National Food & Drink Code of Conduct specifically states that:

It is "forbidden as it aims at misleading the consumers, and is persecuted as misleading. Any statement or advertising, in any way, of a foodstuff with which it is directly or indirectly implied that the food in question possess properties, not actually present in it during consumption.

Or

That this (food) is appropriate for the prevention and/or cure of:

Alcoholism, hair loss, appendicitis, arteriosclerosis, collapse, prostate disease, dysentery, cancer, spasms, diabetes, menstruation disorder, epilepsy, gangrene, glaucoma, arthritis, heart disease, high pressure, hernia, low pressure, flue, neuropathy, leukaemia, liver disease, nausea and other pregnancy related conditions, obesity, pleurisy, pneumonia, poliomyelitis, rheumatic fever, rheumatic arthritis, psoriasis, septicaemia, sexual dysfunction, tetanus, thyroid disease, tuberculosis, tumours and oedema, digestive ulcer and in general colitis, aphrodisiac diseases as well as relevant diseases and conditions.

3. Ethical Claims

No definition of an 'Ethical Claim' is provided in Greek legislation.

B. LEGISLATION IN PLACE

1. Nutritional Claims

a. Directive 79/112 on Labelling of Foodstuffs[6]

Article 2 of the EU directive 79/112 is included identical in the Greek legislation under Article 11 of the National Food & Drink Code of Conduct[7] (see Annex 3).

[6] Reference only to the consolidated version of this directive (including all amendments).
[7] Article 11 is amended with decisions of the Supreme Chemical Council No. 2206/85 ΦΕΚ 49/Β/86 and No. 804/90 ΦΕΚ 104/Β91.

Specifically, Article 11, par 2. states that "The labelling and methods used must not: be such as could mislead the purchaser to a material degree, particularly as to the characteristics of the foodstuff and, in particular, as to its nature, identity, properties, composition, quantity, durability, origin or provenance, method of manufacture or consumption, by attributing to the foodstuff effects or properties which it does not possess, by suggesting that the foodstuff possesses special characteristics when in fact all similar foodstuffs possess such characteristics".

Article 5, par. 3 of the Directive has also been adopted as such by the Greek legislation under Article 11, par. 4c of the National Food & Drink Code of Conduct.

Specifically, par. 4c of the Article states that:

"The name under which the product is sold shall include or be accompanied by particulars as to the physical condition of the foodstuff or the specific treatment which it has undergone (e.g. powdered, freeze-dried, deep-frozen, concentrated, smoked) in all cases where omission of such information could create confusion in the mind of the purchaser. Any foodstuff which has been treated with ionising radiation, if and when this is allowed, must bear the indication ("epexergasmeno me ionizousa aktinovolia" or "epexergasmeno")[8].

Additional provisions regarding nutritional claims are given by the Greek legislation under Article 10 of the National Food & Drink Code of Conduct[9]. These provisions are present in par. 4-16 of Article 10 (see Annex 2) and include a number of measures covering claims on proteins (i.e. claims as "exceptional protein quality"), on dietary products (i.e. claims as "thin, slim, light, low calorie, carbohydrate free")

b. Directive 90/496 on Nutrition Labelling of Foodstuffs

Article 11a of the National Food & Drink Code of Conduct (on Nutrition Labelling)[10] includes additional provisions to Article 11 of the same Code aiming to harmonise Greek legislation on the issue of nutrition labelling for foodstuffs to Directive 90/496 of the Community.

All provisions of the Directive 90/496 are, therefore, included identical in the Greek legislation under Article 11a and no additional provisions (either more or less strict) are present. Provisions included in Articles 1.4.b, 2 and 3 of the Directive (mentioned above) are presented as such in Article 11a, par. 2b, par.3 and par. 4 of the National Food & Drink Code of Conduct respectively (see Annex 1).

Specifically, par. 4 of the Article is of major interest as it states that nutritional claims allowed are only those referring to the calorific value and the nutritional substances, as these are presented in paragraph 2.a.ii of the same article and, to the substances belonging in one of the categories of these nutritional substances or constitute their components.

[8] In English: "treated with ionising radiation" or "irradiated".
[9] Article 10: Statement and Advertising of Foodstuffs.
[10] Decision no. 843/91, ΦΕΚ, 80/B/12.2.92 page 84 of the Supreme Chemical Council

c. Directive 89/398 on Foodstuffs for Particular Nutritional Uses

Ministerial Decision no. A2E/5478 FEK 189/99 was introduced earlier this year with the aim to harmonising Greek legislation with EU Directive 89/398. All provisions of the Directive are included identical in the Greek legislation under Articles 1-12 [11] page 2663-2665 (see Annex 4).

Article 4.1 of the Directive provides for the issuance, by the Member States or the EU, of specific legislative documents for each different category of individuals (e.g., infants, athletes, etc.) as stated and analysed in par. 1.2.b of the same directive.

There is also an additional legislative document regarding baby foods - FEK 585/B/9.8.93, no. Υ3Δ 1510 page 6399 (see Annex 5) - following the provisions included in Article 4.1 of Directive 89/398 and the succeeding Directive 91/321 on baby foods. Of interest:

1. Article 5, par 3. states that "the use of terms such as humanised, maternalised or other similar terms is forbidden"
2. Article 5, par 5. suggests that "the labelling of baby-foods should not include pictures of babies or other pictures or texts that idealise the use of the particular product".
3. Article 5, par 6. states that "the labelling (of baby foods) may include claims relating to special composition of a baby-food as regards the cases mentioned in Annex IV and according to the terms determined therein".

Specifically Annex IV (see Annex 5) provides for 6 categories of claims (e.g. adapted protein, enriched iron, etc.) on baby foods as well as the relevant criteria for substantiating them.

d. Directive 84/450 on Misleading Advertising

The Directive aims at providing the grounds for the effective control of misleading advertising by the Member States and is introduced in its entirety in the Greek legislation. The latter is more detailed, but does not make any direct references to claims (see Annex 7).

2. Health Claims

a. Directive 65/65 on Medicinal Products

Article 1 of the directive on medicinal products seems to be of particular interest to the issue of claims. This is mainly due to the definition given for what is a medicinal product, leading to the conclusion that the "dividing line between a medicinal product and a foodstuff is very thin".

Directive 65/65 is included in Greek legislation under Ministerial Decision no. A6 9392/91, FEK B number 233 of 07/04/1992 page 2258 (see Annex 6). This particular law calls for "the harmonisation of Greek legislation to the corresponding Community legislation in the fields of production, importing and circulation of medicinal products".

[11] Which replaced ministerial decision no. 1552/90 of 29.11.1990 FEK B number 786 of 13.12.1990

Article 1 of Directive 65/65 is identical to Article 2 of Law A6a/9392/91. According to the latter:

1. Medicinal Product: Any medicine already produced that goes in circulation under a specific name and specific packaging.

2. Medicine: Any substance or combination of substances presented for treating or preventing disease in human beings or animals.

As a medicine is also considered any substance or combination of substances that could be supplied to a human being or animal, with the aim to perform a medical diagnosis or to restore, improve or modify organic functions of the human being or animal.

3.Substance: Any substance regardless of origin that might be:
Human (i.e. human blood, human blood derivatives etc),
Animal (i.e. toxins, animal excretions),
Vegetable (i.e. vegetable parts, vegetable excretions etc.).

Note: It is also worth mentioning here that those articles of the Directive 65/65 related to labelling (i.e. Articles 13- 20) are also included identical in the Greek legislation (see Annex 6).

b. Directive 79/112 on Labelling for Foodstuffs

Article 2, par. b of the EU Directive is included identical (word-by-word) in the Greek legislation under Article 11, par 2, ii of the National Food & Drink Code of Conduct (see Annex 3).

c. Directive 89/398 on Foodstuffs for Particular Nutritional Uses

Article 6 of the EU directive is included as such (it states that in the labelling, presentation and advertising of these products it is forbidden to "attribute properties for the prevention, treatment or cure of human disease to such products or imply such properties") under Article 7, par. 1 of Ministerial Decision no. A2E/5478 FEK 189/99 page 2664 (see Annex 4), and no additional provisions, whatsoever, are present.

d. Directive 84/450 (+amendment 97/55) on Misleading Advertising

In an attempt to harmonise Greek legislation with the corresponding EU directive on Misleading Advertising, Ministerial Decision no. 5206/89 has been introduced.

Greek legislation does not include any provisions related to Article 6 regarding the verification procedure for misleading advertising and the relevant proof adduced.

Greek legislation includes some provisions, under Article 4 (Ministerial Decision no. 5206/89) on Misleading Advertising, relevant to our study but in a more general framework (see Annex 7). These set up in general the procedure to be followed in each case of a misleading advertising (i.e. court procedures, administrative bodies, independent organisations). It should be noted that the above article conforms to Article 4 of the EU

Directive, which leaves at the discretion of each Member State to determine the exact procedure to be followed (i.e. judicial procedure or resolution via an administrative body).

Greek legislation, under Article 3, par.2 of Law 5206/1989 (and also under Article 9 of 2251/1994 on Consumer Protection), provides for additional criteria under which an advert can be considered misleading (see Annex 8).

e. Directive 89/552 on Television Broadcasting

The above-mentioned Community directive is adopted in Greek legislation under Ministerial Decision (no. 236/1992 and amendment 231 of 19/20.6.1995) on 'Television broadcasting rights in Greece' (see Annex 9). No additional provisions were revealed.

Article 6 par. 1 of the Greek law states clearly that "surreptitious advertising" is forbidden.

Article 7, par.2 of the same law states that "television advertisements of alcohol drinks should conform with the following criteria:

(a) Neither address specifically to minors, nor -particularly- show minors consuming such drinks,
(b) Not relate the consumption of alcohol drinks to improved physical performance or the driving of vehicles,
(c) Not give the impression that consumption of alcohol drinks favours social or sexual success,
(d) Not insinuate that alcohol drinks have therapeutic properties or that they act as stimulants, tranquillisers or appeasers,
(e) Not encourage the unlimited consumption of alcohol drinks and not provide a negative picture of those not consuming such drinks or consuming them within certain limits,
(f) Not emphasise as an advantage of such drinks, their increased capacity in alcohol".

3. Ethical Claims

We could not find any direct legislation referring to ethical claims. The assumption is that they would fall under the misleading advertising Directive implementing rules.

C. EXISTING PROHIBITIONS, RESTRICTIONS AND EXEMPTIONS

1. Nutritional Claims

The analysis was based on nutritional or health claims that are allowed to be made or not and relevant restrictions, prohibitions and exemptions relating to this general rule are presented.

a. Statement - Advertising of Foodstuffs. (Article 10, National Food & Drink Code of Conduct) - (see Annex 2)

i. Prohibitions-Restrictions

Paragraph 3 of the article states that it is "forbidden as it aims at misleading the consumers, and is persecuted as misleading any statement or advertising, in any way, of a foodstuff, with which it is directly or indirectly implied that the food offered for consumption by a particular

producer, is particularly rich (or in some cases poor) in one or more of its basic nutrient ingredients, or that it contains these (ingredients) in higher, or in some cases lower, ratios than usual, even if this is real, if these ingredients are included in a percentage that lies within the agreed limits, determined by the Code, for the corresponding type of food.

As such, a misleading claim, is also considered any writing on the packaging regarding a foodstuff's content of a certain ingredient, at a spot clear and distant from the one, where the food's composition is provided".

Par. 6 of Article 10 forbids the use of the word 'protein' as part of the name of any foodstuff.

Additional restrictions are included in par. 7- 16 of the article. These include a number of provisions for issues like:

- The statement - advertising of a foodstuff that makes a claim on the nutritional value/quality of a protein is permitted only following approval of NPO according to a number of nutritional criteria.
- The circumstances under which it is possible to claim that a foodstuff is low/poor in carbohydrates. E.g. special dietary foods claiming to be appropriate for low-carbohydrate diets must not include more than 0.25% of assimilated carbohydrates as a maximum limit.
- Food categories involving claim such as slim, light, line etc.
- Products that claim 'low/poor calorific values'
- Products originating from a particular geographical location while circulating in the market under the name of another, etc.(see Annex 2).

ii. Exemptions

Paragraph 5 of the article exempts from the provisions included in par. 3 of the same article (mentioned above), cases where such a claim has prevailed or is included in the code of conduct for the distinction of the product (i.e., Salted Butter, Skimmed Milk, etc.).

b. Labelling-Presentation of Foodstuffs (Article 11, National Food & Drink Code of Conduct) - (see Annex 3).

i. Prohibitions-Restrictions

Par. 2 (I) of the article forbids the labelling of a foodstuff in a way that is likely to mislead the consumer particularly:

- As regards the foodstuff's characteristics, especially its nature, identity, properties, composition, quantity, place of production or origin, method of production.
- By attributing to the foodstuff effect or properties which it does not possess.
- By stating that a foodstuff has special characteristics when these (characteristics) are present in all similar foodstuffs.

Par. 6a defines the terms 'no colours', 'no preservatives' or equivalent claims can be included on the packaging of a foodstuff, if and only if, the foodstuff in question does not include such substances wherever these may come from.

Additional restrictions regarding flavourings are included in Annex 3, Article 11, page 42 of the same article (see Annex 3).

c. Nutrition Labelling of Foodstuffs (Article 11a, National Food & Drink Code of Conduct) - (see Annex 1).

i. Exemptions

Par. 1b of the article exempts natural mineral waters (destined for human consumption) as well as dietary supplements and fortified foods from the provisions related to the nutrition labelling of foodstuffs and consequently nutritional claims.

d. Foodstuffs for Particular Nutritional Uses (Ministerial Decision no. A2E/5478 FEK 189/99) - (see Annex 4).

i. Prohibitions-Restrictions

Article 2, par. 4 states that it is forbidden for foodstuffs of ordinary consumption to be labelled, presented or advertised as:

- dietary' or 'for diet' and the use of these words on their own or together with others for their distinction.
- with any other labelling methods, likely to give the impression that these are products that fit the description of products for particular nutritional uses; as defined in par. 1 and 2 of the same article.

Moreover, there is an additional legislative document[12] that includes a prohibition regarding foodstuffs for particular nutritional uses[13].

Thus, according to Article 5 (on presentation - advertising), "the labelling, advertising and, generally, presentation of such products shall not include any statements regarding the speed and extension of weight loss, likely to occur after consumption of these products, or the reduction of the feeling of hunger or the increase of the feeling of satisfaction".

ii. Exemptions

In Article 2, par. 5 of Ministerial Decision no. A2E/5478 FEK 189/99, it is stated that "for foodstuffs for ordinary consumption, in case these are considered appropriate for particular nutritional purposes, it is allowed to carry relevant claims according to the procedure outlined in Article 5 of this Min. Decision".

e. Baby Foods (Ministerial Decision no. 2039736/4719/0022)[14] - (see Annex 5).

i. Prohibitions-Restrictions

[12] no. YEA Y3E/5497 15.10.97/13.3.98) - (see Annex 17).
[13] This particular law aims to harmonise Greek legislation with the corresponding Community directive 96/8/EC regarding "foodstuffs intended to be used in 'reduced-calories' diets for the loss of weight"
[14] See annex for full text.

Article 2 (on circulation - disposal), par. 1 states that "no other products, except from those that fulfil the requirements for baby foods- should be allowed to circulate in the market or be presented in any other way as appropriate for satisfying the nutritional needs of babies during the first 4-6 months of their lives...".

Article 5 (on labelling), par. 3 states that "the labelling of foodstuffs for babies should be carried out in such a way so as to provide all the necessary information for the right use of the product and should not discourage breast feeding".

Moreover the same paragraph forbids the use of the terms "humanised" and "maternalised". The term "adapted" can only be used in accordance with the provisions of paragraph 6 of the same article.
Par. 5 of the same article states that "the labelling of baby foods should not contain pictures of babies or any other pictures or objects that will idealise the use of the product".

ii. Exemptions

Article 5, par. 5 of the above Ministerial Decision (that forbids the use of pictures of babies) exempts the use of shapes, which will assist in the identification of the product and which present the guidelines for consuming it.

f. Food Supplements (Ministerial Decision no. Y8/10170 FEK 935/95 page 12218) - (see Annex 10)

i. Prohibitions-Restrictions

Article 6, par. 2 (on presentation - advertising) of this law prohibits any "misleading presentation, advertising and labelling as far as composition, names, terms, words, phrases or pictures are concerned".

g. Misleading Advertising (Ministerial Decision no. FEK. 5206/89) - (see Annex 7).

i. Prohibitions-Restrictions

Article 4 of the law forbids misleading advertising.

h. Television Broadcasting (Ministerial Decision no. 236 10/16.7.92) - (see Annex 9)

i. Prohibitions-Restrictions

Article 6, par. 1 of the Greek law forbids "surreptitious advertising".

i. Mineral Waters (Ministerial Decision no. 433 FEK 163/83 of 9.11.83.) - (see Annex 11).

i. Prohibitions-Restrictions

Article 8, par. 2 forbids the trading of a natural mineral water, originating from one source, under many different brand names.

Article 9, par. 1 states that it is "forbidden, either on the packaging or label, or in any form of advertising, the use of brand indications, industrial or commercial labels, pictures or other symbolic parts, or not, which:

a) for a natural mineral water, insinuate a characteristic, which it does not possess, particularly as regards the origin, license date for sale, the analysis results and also any relevant statements regarding guarantees of authenticity;
b) for a packaged drinking water, not conforming to the terms of paragraph1 of section I, likely to create confusion with a natural mineral water and mostly the indication "mineral water".

ii. Exemptions

Article 9, par. 2b exempts the use of indications that conform to a number of criteria presented in section 3 of Ministerial Decision no. 433 FEK 163/83 of 9.11.83.

2. Health Claims

a. Statement - Advertising of Foodstuffs (Article 10, National Food & Drink Code of Conduct) - (see Annex 2)

i. Prohibitions-Restrictions

Article 10, par. 2 states that it is "forbidden as it aims at misleading the consumers, and is persecuted as misleading. Any statement or advertising, in any way, of a foodstuff with which it is directly or indirectly implied that the food in question possess properties, not actually present in it during consumption or that this (food) is appropriate for the prevention and/or cure of:

Alcoholism, hair loss, appendicitis, arteriosclerosis, collapse, prostate disease, dysentery, cancer, spasms, diabetes, menstruation disorder, epilepsy, gangrene, glaucoma, arthritis, heart disease, high pressure, hernia, low pressure, flue, neuropathy, leukaemia, liver disease, nausea and other pregnancy related conditions, obesity, pleurisy, pneumonia, poliomyelitis, rheumatic fever, rheumatic arthritis, psoriasis, septicaemia, sexual dysfunction, tetanus, thyroid disease, tuberculosis, tumours and oedema, digestive ulcer and in general, colitis, aphrodisiac diseases as well as relevant diseases and conditions.

b. Labelling - Presentation of Foodstuffs (Article 11, National Food & Drink Code of Conduct) - (see Annex 3).

i. Prohibitions-Restrictions

Par. 2a.ii of the article states that labelling should not "attribute to the foodstuff properties for the prevention, treatment or cure of diseases, or insinuate such properties'.

ii. Exemptions

Par. 2a.ii exempts mineral waters and foodstuffs for particular nutritional uses from the above mentioned prohibitions - restrictions.

c. Food Supplements (Ministerial Decision no. Y8/10170 FEK 935/95 page 12218) - (see Annex 10).

i. Prohibitions-Restrictions

Article 6, par. 3 (on presentation - advertising) states that "the writing of claims or indications that insinuate directly or indirectly the prevention - cure of diseases, preservation or change of physical functions, in the labelling, advertising or presentation of food supplements is forbidden".

d. Television Broadcasting (Ministerial Decision, no. 236 of 10/16.7.92) - (see Annex 9).

i. Prohibitions-Restrictions

Article 7, par.2 of this ministerial decision states that "television advertisements of alcohol drinks should :

(a) Neither address specifically to minors, nor - particularly - show minors consuming such drinks,
(b) Not relate the consumption of alcohol drinks to improved physical performance or the driving of vehicles,
(c) Not give the impression that consumption of alcohol drinks favours social or sexual success,
(d) Not insinuate that alcohol drinks have therapeutic properties or that they act as stimulants, tranquillisers or appeasers,
(e) Not encourage the unlimited consumption of alcohol drinks and not provide a negative picture of those not consuming such drinks or consuming them within certain limits,
(f) Not emphasise as an advantage of such drinks, their increased capacity in alcohol".

e. Mineral Waters (Ministerial Decision no. 433 FEK 163/83 of 9.11.83.) - (see Annex 11).

i. Prohibitions-Restrictions

Article 9, par. 2a forbids all indications that attribute to a natural mineral water, properties of preventing medical treatment or of curing a human disease. Par. 2c of the same article forbids indications such as "enhances digestion" or other similar indications related to the effects of water on the functions of the human organism, even if these are not inconsistent with the requirements of par.2a of the same article or cover the presumptions determined in par. 2b.

Examples:

In practice, the relevant Greek authorities - the State Laboratory for General Chemistry and in some cases the National Pharmaceutical Organisation - have prohibited the use of specific claims (nutritional and/or health) on foodstuffs.

Following is a representative list of examples, which may further assist us in identifying the viewpoint of the Greek State on this issue:

1. "Strong milk".
2. "The only fresh milk which contains iron and vitamins B12 and C". The word only was prohibited.
3. "Fresh product", referring to a yoghurt.
4. "Rich in proteins", referring to instant soups.
5. "High quality and healthy ingredients".
6. Prohibition of the use of word "protein" as part of a spaghetti brand name.
7. "For a healthy nutrition", referring to a cereal product for general use.
8. "For diabetics", referring to candies.
9. "Low calorific value", referring to sweet.
10. "Soothing, relieving digestive ..../upset stomach for babies", referring to foodstuff for general uses (beverage).
11. "Replenishes lost energy", referring to a beverage (juice).
12. "Stress relieving, increases physical endurance", referring to a drink.
13. "...offers all ingredients necessary to the human body", referring to a common milk.
14. "It is the first fresh milk, enriched with vitamins A, D and E which give beauty, vitality, glow and health".
15. "Gives vitality and strength to your body, beauty and glow to your skin", referring to milk.
16. "...reinforces the immune system", referring to a milk enriched with vitamins A, D and E.

D. POLICY DEVELOPMENTS AND STAKEHOLDERS' POSITIONS

Overall, the Greek authorities have not realised the importance of the issue of claims per se and in the general context of consumer protection and free trade in the EU Member States. Consequently, Greece's policy regarding claims has not been developed so as to efficiently regulate related issues and provide for tailored measures to handle the current situation in the country and confront problems that may arise.

A contributing factor to this Greek State's policy is the absence of an official and uniform organisation/body to tackle all issues relevant to the control of foodstuffs and therefore, claims. At this stage, given the lack of ability and promptness to provide solutions on consumer protection (particularly for the Food & Drink Industry), the State is in the process of establishing a relevant body. A process that is expected to proceed rather rapidly after the considerable public unease that followed the Belgium dioxin crisis on foodstuffs. So far, however, the only action initiated by the State on the issue of claims is that it conforms to the applicable Directives of the EU.

The Consumer General Secretariat of the Ministry of Development is the authority that has initiated the efforts to set up the first Uniform Foodstuffs Control Board in Greece. This is a project, which was conceptually formulated in the last decade. The delay for its implementation lies in the difficulty to orchestrate the variety of organisations involved and

the disparity of their responsibilities. The Board, which will probably come into effect possibly by the end of this Summer (the legislative document still needs to be concluded) will consist of a Board of Directors, a National Council for Foodstuff Policy and a Scientific Committee. It will function under the authority of the Ministry of Development and will only deal with packaged foodstuffs. Furthermore, a number of consumer organisations, industry representatives, as well as the National Pharmaceutical Organisation and the State Laboratory for General Chemistry will participate in the workings of the Control Board.

This Control Board will serve as a starting point so that the issue of claims is more closely monitored by the State and consequently dealt with via clearly defined administrative channels. This will be a co-ordinated effort, as consumer organisations and NGO's will play an active role in order to serve its objective in a comprehensive and efficient way.

From the viewpoint of consumer organisations, the issue of claims is inefficiently approached by the State. At the same time, lack of knowledge on their behalf has prevented them from thoroughly informing consumers on the possible issues that may arise due to the gaps in the relevant regulatory documents. Following our contacts with consumer organisations, some of them were sensitised and decided to take action by informing and educating Greek consumers. They are also in favour of the establishment of such a Control Board, as this will further enhance consumer protection.

The limited resources of the Greek State to deal with the issues arising in the Food & Drink Industry in general, and in regards to claims on foodstuffs, shows an apparent lack of consumer protection. The public sector authorities responsible for consumer protection further reinforced our conclusion, by clearly admitting that the control systems in place for claims needs improvement and that certain sections of the Greek legislation relating to Food & Drink issues are outdated. Their comment was that Greek legislation has to conform to the current market reality in order to practically assist the relevant authorities to perform their duties effectively and consistently.

Interestingly, there is a specific case relating to a type of honey claiming to have fortifying properties, which was approved by the State Laboratory for General Chemistry but at the same time rejected by the NPO. Interesting to note that this claim was approved, although the Greek law does not permit health claims per se. This probably constitutes the most supportive evidence that the State does not provide for a complete and reliable verification system and cannot, therefore, take impartial and fair decisions.

Public sector representatives expressed the wish to see all issues relating to claims being regulated at EU level. It is their belief that a detailed EU document that could serve as a sanction would help Member States define the relevant boundaries on claims and harmonise their legislation in an appropriate way, which does not leave any grey areas unresolved. However, it was also suggested that further regulation should avoid being 'suffocating'. This should occur in a way so as to literally protect consumers instead of confusing them with the variety of claims that may appear on the market. On the other hand, the industry's concerns should also be accounted for, as additional limitations imposed on foodstuff may in practice constitute a barrier to trade.

According to the consumer organisations' viewpoint, consumer rights are not effectively protected and the action taken by the former is becoming somewhat restricted. This occurs

due to the fact that the control system is complicated and there are many overlaps of responsibility between the various competent bodies.

Other NGOs, such as the Hellenic Advertising Agencies Association, are against further regulation of claims and their incorporation in the EU Directive on Misleading Advertising. It is their belief that this would be highly dysfunctional and would ultimately lead to barriers to trade. Therefore, their suggestion is that self-regulation would be the best solution. If the law becomes more specific and strict on claims, it may restrict to a great extent Food & Drink manufacturers that use more technologically advanced methods than others for the improvement of their products.

III. VOLUNTARY INSTRUMENTS USED

A. VOLUNTARY INSTRUMENTS IN PLACE

The Hellenic Advertising Agencies Association has issued a Code of Conduct, which is binding for all its members as well as the media. This document outlines the general principles to be followed by all parties concerned regarding advertising. It also makes reference to misleading advertising and indirectly to the claims issue (Article 4) by stating that "adverts should not include statements or visual presentations, that either directly or indirectly...may mislead the consumer..." (see Annex 12).

The Federation of Hellenic Food Industries (SEVT) as a member of CIAA conforms to all rules and regulations as these are adopted by all other members.

B. DEFINITIONS USED IN THE VOLUNTARY INSTRUMENTS

There is no definition of a claim in the above-mentioned code.

C. VOLUNTARY INSTRUMENTS ACCEPTED/RECOGNISED BY THE AUTHORITIES

The Hellenic Advertising Agencies Association Code of Conduct is accepted and recognised by the Greek authorities as the official self-regulatory document dealing with the control of advertisements (following the guidelines provided by the relevant Greek legislation [15]).

The same applies to all rules and regulations adopted by SEVT as a member of CIAA.

IV. VERIFICATION SYSTEMS

A. CRITERIA FOR SUBSTANTIATING CLAIMS

Overall, the National Food & Drink Code of Conduct and other relevant legislative documents do not provide any criteria for substantiating claims in particular. Specifically, there is no list of documents mentioned in relevant Greek legislation to determine the necessary proof that needs to be adduced in order to substantiate a claim made on a

[15] See Annex 12.

foodstuff. On the other hand, it is considered inherent that the manufacturer who wishes to use a certain claim is in a position to defend this with scientific documentation.

The only legislative document clearly providing for specific criteria for substantiating certain claims is the one referring to baby foods. In particular, Annex IV included in Ministerial Decision no.Υ3Ε/3452, ΦΕΚ 1040/Β, 25.11.97, provides for characteristics which justify the following claims:

1. Adjusted protein
2. Low sodium capacity
3. Saccharine free
4. Only lactose included
5. Lactose free
6. Enriched iron
7. Reduces the risk of allergies in milk proteins (see Annex 13 for Annex IV)

Moreover, a number of criteria are established in Article 11a, par. 3b, 4 and 5 of the National Food & Drink Code of Conduct, relevant to nutrition labelling. These refer to the energy value of the product, the quantity of proteins, carbohydrates, fat, saturated fat acids, sodium etc., depending on the claim made (see Annex 1).

B. LEGAL/ADMINISTRATIVE SYSTEMS FOR VERIFYING CLAIMS

A formal system and/or organisation responsible for the control of foodstuffs and claims does not exist in Greece. Relevant controls fall under the competence of various public organisations such as the Ministry of Development, the State Laboratory of General Chemistry and the National Pharmaceutical Organisation (NPO). There is an evident overlap of responsibility between all the above mentioned organisations, especially between the State Laboratory for General Chemistry and the National Pharmaceutical Organisation. The majority of relevant controls is actually conducted by the State Market Inspection Service (Ministry of Development, Directorate General for Commerce) through the procedures provided for in the State Market Inspection Code (see Annex 14).

A State Laboratory for General Chemistry

SLGC is responsible for the control of ordinary foodstuffs and subsequently of nutritional claims. The authority responsible to conduct controls (in most cases, the State Market Inspection Service in collaboration with the responsible Chemist Service of the SLGC) forwards its final report to the relevant authorities of the SLGC.

All products, which contain ingredients that are not addressed by the law, are characterised as not normal and the relevant results are submitted to the District Attorney responsible. In this case, the producer/manufacturer is entitled to appeal against the decision and ask for the revision of all relevant controls, within 48 hours. The revised control test may be conducted in presence of a private chemist appointed by the producer/manufacturer. In case of conflicting opinions between the two chemists, the issue is forwarded to the Supreme Chemical Council, which studies the two conflicting reports and submits them to the District Attorney.

In general, product samples collected by the State Market Inspection Service for inspection, are submitted to the SLGC for control regarding the quantity and quality of ingredients, relevant labelling and claims.

B. National Pharmaceutical Organisation (NPO)

The National Pharmaceutical Organisation (NPO) is the competent body for the control of foodstuffs for particular nutritional uses, including relevant claims. According to ministerial decision A2E/5478, FEK 189/B, 5.3.99, Article 6, setting the general guidelines for the control of all foodstuffs for particular nutritional uses (additional and more specific provisions have been envisaged for foodstuff categories included in Article 11 of the document - see Annex 4)[16], such products are subject to control by the National Pharmaceutical Organisation. Companies that wish to sell similar products have to notify the product to the relevant authority. Specifically, companies have to submit:

a) A sample of the product
b) Evidence regarding the producer, the composition and the labelling, in order to check whether production and disposal conform with the relevant legislative provisions; and
c) Scientific studies and relevant documents, in case it is considered necessary to prove whether the product has the purpose for which it is supposed to serve.

No reference is made to the control of claims, in particular. However, claims are considered part of the labelling and are also related to the particular nutritional purpose of the product in question. Consequently, claims are examined in conjunction with the relevant control procedure applicable to products for particular nutritional uses.

Health claims are not officially allowed by the Greek law. However, in case a health claim is made on a product or a company asks for a certain health claim to be approved, the decision making procedure lies within the jurisdiction of the National Pharmaceutical Organisation. In practice the NPO has issued in the past licences regarding health claims.

Two recent examples of health claims approved so far by the NPO are:1) Kellogg's All Bran; claim regarding fibres and their beneficial effect on the physiological function of the intestines and 2) A specific chewing gum that has a claim on its packaging about helping avoid teeth's decay.

Overall, it should be mentioned that there is a fine line between the responsibilities of these two competent bodies, which are very often intermingled, thus creating a grey area for this research.

1. Pre-Clearance Rules / Guidelines

No pre-clearance rules exist in Greece officially.

2. Post-Clearance Rules / Guidelines

[16] For further details, refer to Ministerial Decision Y6/10170 on the circulation of food supplements, ΦΕΚ 935/B, 13.11.95, article 4 and Ministerial Decision Y3E/3452 on baby foods, ΦΕΚ 1040/B, 25.11.97, article 2.

a. Civil or criminal law redress procedures

The legal procedure for the verification as to whether a claim made by a producer/manufacturer is misleading or not is as follows. Following the Greek Consumer Protection Legislation (Law 2251/1994) a consumer wishing to sue for a misleading claim is obliged to do so through a consumer organisation. This is because the ultimate goal of the State is to protect the interest of the general public/consumers. Such cases are submitted to the civil courts and are most often handled through the procedure of provisional measures. Following the application of these provisional measures, a product may be banned from circulation and compensation is given to the consumer.

Apart from the civil courts, such cases are often submitted to the criminal courts for fraud. According to Article 57 of the Greek civil code on "Protection of One's Personality", an individual consumer can also stand before a criminal court and request compensation from the producer/manufacturer of a product for a misleading claim.

b. Specific procedures for claims

There is no specific procedure applicable to claims only. The procedure followed is the one applied to all consumer protection cases.

c. Out-of-court procedures

i. Consumer Protection Law 2251/1994

According to law 2251/1994 on Consumer Protection, every Prefecture is responsible to set-up a Committee of Out-of-Court Settlement, which would resolve differences between vendors and consumers or consumer organisations (Article 11, par. 1).

ii. Procedure defined by administrative bodies

The Hellenic Advertising Agencies Association has set-up two committees that deal with complaints and are responsible for the resolution of issues that concern misleading advertising and misleading claims. According to the Association's internal regulation procedures, all complaints are directed and handled by the First Degree Committee for the control of advertisements and in the case that an appeal is filed for a decision, this case is submitted to the Second Degree Committee.

The primary function of the two Advertising Standard Control Committees is to examine alleged breaches of the Greek Advertising Code. In the occasion that either the advertising company or the company being advertised refuse to implement the decision of the Committees, the latter can request the discontinuation of the advertisement directly from the media broadcasting it.

iii. Internal settlement

In practice, there exists a number of cases, which are resolved via out-of-court procedures. These involve the internal settlement of a dispute between two competing companies or between a company and a consumer organisation.

d. What are the administrative/legal costs?

There is no fixed cost for going to court in Greece. This depends on the case handled, the time required and actually spent in order to reach a resolution. There are, however, some fixed costs that apply to all cases. These include the court filing costs (deposition of case files and documents, stamps) and the court hearing costs (for the legal representation to court), which amount to a maximum of 100.000 DRS.

In case the plaintiff asks for compensation there is also a fixed cost for going to court, which amounts to 7,5/1.000 of the compensation amount. As a general statement, a lawyer in Greece should charge a minimum of 20.000 DRS. per hour in defending a case. The Greek Lawyers Association has set this amount as a benchmark. Since there are no cases available on claims, no further information can be provided as to the fixed amount such a case would actually cost.

C. LEGAL PERSONS ENTITLED TO TAKE LEGAL ACTION

According to Law 2251/1994 on Consumer Protection, consumer organisation are entitled to take legal action against misleading claims and represent consumers both in court and in out-of-court procedures (Article 9, par. 1).

However, according to Article 57 of the Greek civil code on "Protection of One's Personality", a consumer can sue individually the producer/manufacturer of a product for a misleading claim with the accusation of fraud (before criminal courts) and also request compensation.

According to information gathered from our interviews with voluntary instruments, it seems that part of the legal action was taken by a consumer organisation through the procedure of a collective lawsuit, while in other cases legal action was taken from one company against another competitor company.

D. BURDEN OF PROOF

a. Burden of proof

According to the legislative documents dealing with Unfair Competition (Law 146/1914) and Consumer Protection (Law 2251/1994) it is not clear with whom lies the burden of proof. Evidently, Greek legislation does not define whether the producer/manufacturer or the consumer/consumer organisation have the ultimate responsibility to prove that a claim is misleading or not.

However, public sector representatives and NGOs indicated that the burden of proof lies in practice with both parties.

b. Proof to be adduced

Greek legislation does not provide for a list of documents that have to be submitted by a producer/manufacturer and/or consumer/consumer organisation to court as proof against/for a misleading claim. However, it is evident that a producer/manufacturer has to keep record of all documents relevant to the production methods and composition, labelling standards

and requirements and, therefore, claims. On the other hand, the consumer/consumer organisation needs to defend its case by submitting all relevant evidence in the form of documents to prove the alleged damage or loss.

E. APPLICABLE PENALTIES

1. General Rule

As a general principle, according to Law 2251/1994 on Consumer Protection, the penalties that are inflicted on the producer/manufacturer by the Ministry of Development (Directorate General for Commerce) for any violation of the current law range between 500.000 DRS to 20 million DRS. In the case of repetition of an offence, the maximum penalty limit doubles, while in the case of further repetition of an offence, the Deputy Minister of Commerce, following the recommendations of the National Consumers' Council, may order the shutting down of a company (or part of its operations) for up to one year (Law 2251/1998, Article 14., par. 3).

2. Penalties imposed by NPO (National Pharmaceutical Organisation)

According to the Law 1316/11.11.83, article 33, paragraph 3, the penalties that are inflicted on a producer/manufacturer who breaks the law in regards to the mandatory indications of the labelling of medicinal and other products (such as dietary foods, infant milk) reach 500.000 DRS. In the case of repetition of the offence, the penalty rises to 1 million DRS and the company may be shut down.

V. CASE LAW

Given that the claims issue in Greece is still in its embryonic stage of development and all cases so far have been reported on an ad-hoc basis, there is an evident lack of information. The fact that Greek courts of Justice are not yet fully accustomed with modern information technology systems is in itself another contributing factor to this inefficiency and, therefore, a limitation to our study.

There is no pertinent case law available in Greece for all the above mentioned reasons. Additionally, representatives from consumer organisations could not recall of any cases relating to claims, although they referred to a limited number of cases on food and drink issues in general, that reached the courts.

Case 1: A well known slimming pill called SLIM was banned from circulation following a collective lawsuit that was filled against the company by the General Consumers' Federation of Greece (G.C.F.G.). This was done on behalf of 2.400 consumers that had called in with complaints about misleading claims (this was the case of the 'miracle' pill that one could take and lose weight). The case was resolved through legal action (civil and criminal courts) and the company was shut down and had to also pay a large fine.

Case 2: One of the largest Greek dairy companies was taken to court by its biggest competitor for a misleading claim. Specifically, the company claimed that its highly pasteurised milk must be preserved only in the refrigerator. Such a claim carries the connotation of a fresh product. This was proved to be a misrepresentation of the specific

product, because when milk is highly pasteurised it is considered as UHT and, therefore, does not need to be preserved in the refrigerator. Following the legal decision that was incriminating, the company withdrew the specific claim from the packaging.

VI. MEANS OF COMMUNICATION

On a theoretical basis, all legislative documents - related to nutritional or health claims - are applicable to all means of communication.

Specifically, Article 10 of the National Food & Drink Code of Conduct, on statement/advertising of foodstuffs states that:

"The provisions included in this article concern the statement or advertising of a foodstuff including any references on or inside the packaging as well as any written or oral statement in the press, radio, television, cinema".

The article goes on to forbid: "Any statement or advertising, in any way, of a foodstuff with which it is directly or indirectly implied that the food in question": "Possess properties, not actually present in it during consumption or "That this (food) is appropriate for the prevention and/or cure of: alcoholism, hair loss, appendicitis, arteriosclerosis, collapse, prostate disease, dysentery, cancer, spasms, diabetes." (see section II.A.2 of this report)".

Article 9 of Law 2251/1994 on Consumer Protection clearly states that misleading advertising is forbidden - and defines the term advertising as "any statement made in terms of commercial, industrial or professional activities".

At this point, however, it is necessary to comment on a possible discrepancy between law and practice based on two facts. First, the absence of a relevant body for the control of claims (both nutritional and health) and second, the very wide spectrum of activities - apart from checking on claims - of the organisations currently responsible for this issue, such as the State Laboratory for General Chemistry and the National Pharmaceutical Organisation.

Consequently, there could be differences as to the strictness and intensity with which the law is applied among the various means of communication.

In television adverts, for example, seen by a much larger percentage of potential consumers than, say, a press release, existing legislation on labelling, advertising and therefore claims is more accurately applied. This, on the other hand, may not be the case with other means of communication, such as information or promotional material, targeting specific segments of the market being therefore "less regulated".

For example, our research revealed the existence of a specific advertising booklet for the Red Bull Energy Drink in which both the nutritional and health claims present are clearly illegal, according to the national legislation on claims. Examples of claims within this promotional leaflet include (a)"enhances the ability to concentrate" (nutritional) and (b) "revitalises brain cells" (health).

As a general comment, it could be stated that there is an excessive number of legislative documents on advertising (including misleading advertising) in all means of communication,

which are also obviously overlapping. More specifically, the provisions on misleading advertising are spread in a wide variety of Greek legislative documents, thus creating confusion as regards the purpose behind their existing differences. This is most probably due to the fact that these legislative documents have an underlying difference in their approach.

VII. STATISTICS ON CLAIMS

Neither the official state authorities nor consumer organisations or industry groups have statistical information on claims.

VIII. ANNEXES

1) Ministerial decision no.843/91 FEK 80 of 19/11/1991, p 846, article 11a of the National Food and Drink Code of Conduct, harmonising Greek legislation with the corresponding EU Directive 90/496 on Nutrition labelling of Foodstuffs.
2) National Food and Drink Code of Conduct, article 10, par 3 (advertising of foodstuffs)
3) National Food and Drink Code of Conduct, article 11 par.2.a.ii (labelling-presentation of foodstuffs)
4) Min. Decision A2E/5478 pages 2663-2665
5) Decision no. 843/91, - FEK 585/B/9.8.93, no. Υ3Δ 1510 page 6399
6) Ministerial Decision No.A6 9392/91, fek B NUMBER 233OF 07/04/1992 PAGE 2258, Which replaced Ministerial Decision no. 1552/90 of 29.11.1990 FEK B number 786 of 13.12.1990.
7) Ministerial Decision no.5206/89 on Misleading Advertising. This particular law aims at harmonising Greek legislation with the corresponding Community directive 96/8/EC regarding "foodstuffs intended to be used in 'reduced-calories' diets for the loss of weight".
8) Law 5206/1989, article3, par.2 and article 9 of 2251/1994 on Consumer and Protection.
9) Ministerial Decision no.236/1992 on Television Broadcasting rights in Greece"
10) Food supplements \Ministerial Decision no.YB/10170 FEK 935/95
11) Mineral Waters Ministerial decision no. 433 FEK 163/83 of 9.11.83
12) Greek Advertising Code
13) Baby Food (amendments) Ministerial Decision no. Y3E/3452 FEK 1040/
14) The State Market Inspection Code
15) Unfair Competition Law no. 46/1914.
16) National Pharmaceutical Organisation. Penalties imposed.
17) Ministerial Decision no. Y3E/5497.

FOOTNOTES

1. Reference only to the consolidated version of this directive (including all amendments).
2. Article 11 is amended with decisions of the Supreme Chemical Council No. 2206/85 FEK 49/B/86 and No. 804/90 FEK 104/B91.
3. In English: "treated with ionising radiation" or "irradiated".
4. Article 10: Statement and Advertising of Foodstuffs.
5. Decision no. 843/91, FEK, 80/B/12.2.92 page 84 of the Supreme Chemical Council
6. This replaced ministerial decision no. 1552/90 of 29.11.1990 FEK B number 786 of 13.12.1990.
7. This particular law aims to harmonise Greek legislation with the corresponding Community directive 96/8/EC regarding "foodstuffs intended to be used in 'reduced-calories' diets for the loss of weight"
8. See annex for full text.
9. For further details, refer to Ministerial Decision Y6/10170 on the circulation of food supplements, FEK 935/B, 13.11.95, article 4 and Ministerial Decision Y3E/3452 on baby foods, FEK 1040/B, 25.11.97, article 2.

IX. DATABASE OF CONTACTS

I. IRELAND

I. EXECUTIVE ANALYSIS

A. INTRODUCTION

The study was well received by all interested parties in Ireland. Those who participated were by and large pleased to see that the European Commission/DG XXIV is taking an interest in these issues, especially as many, particularly in the Irish government, are often under-resourced and welcome EU-level support. There was some concern expressed, however, that this may be simply another in a long line of studies which lead to the setting up of new consultative committees, but which do not bring concrete results. There was a widespread desire that this study should result in real action to address the claims issue.

The following Executive Analysis outlines the key points of interest for the purpose of the study.

B. MEMBER STATE POLICY

1. Nutritional claims

The definition of a nutritional claim is the same as defined in EU law, although claims related to dietary guidelines or healthy diets are not allowed under Irish law, making them somewhat stricter to that of the latest Codex guidelines on nutritional claims. From the authorities' standpoint, the government departments and the Food Safety Authority of Ireland (FSAI), the legislation in place is working well and there is no need for any review. However, this position is not shared by the Irish Business Employers Confederation. They believe that the current legislation is not sufficiently clear, leading to confusion as to what type of nutritional claim can be made.

2. Health Claims

With regard to health claims, these are banned under the national implementing legislation of 79/112, word for word. Nevertheless, the authorities recognise the fact that health claims are being used, but they have neither the human or financial resources to verify and/or bring manufacturers to court.

The Irish Medicines Board (IMB), aware of the growing problem of "borderline" products, has tried to rectify the situation by issuing guidelines on the definition of a medicinal product. In effect, these guidelines, together with a list of non-exhaustive words, which could imply a claim, reinforce the notion that any product, which claims to cure, alleviate or prevent disease, should be considered a medicinal product. The IMB takes into account of ECJ ruling of 1991 (OJ 1991 C219/91), which states that a product which is recommended or described as having preventive or curative properties is a medicinal product, even if it is generally considered as a foodstuff and even if it has no known therapeutic effect in the present state of scientific knowledge.

The FSAI's view is that the EU should clarify such borderline cases and should make reference to Directive 65/65 on medicinal products. At the same, they should issue a positive list of health claims, based on sound science as developed by the FDA in the US, instead of relying merely on guidelines or definitions. They also commented that the burden of proof should lie with the manufacturer, who wanted to add a claim to the list, and a Scientific Committee would consider the evidence put forward. National authorities, or European, could then prosecute on the basis of this list without having to mount a huge scientific case. Furthermore, a pre-vetting system should be set-up, such as is the case of the Novel Foods pre-market authorisation.

There was no apparent support for using the Misleading Advertising Directive as this was deemed to be a too broad based Directive, which would not be suited to such a complex issue.

3. Ethical claims

The issue of ethical claims has received little attention to date in Ireland. There is no legal definition of an ethical claim and no directly relevant legislation.

C. VOLUNTARY CODES OF PRACTICE

1. Nutritional and Health Claims

Whilst there are no voluntary codes of practice on health or nutritional claims, the Irish Business Employers Confederation (IBEC) did initiate the idea of a voluntary code for health claims, along the lines of the UK Joint Health Claim Initiative. The IBEC hopes that the FSAI will support such self-regulation as the best way forward.

However, the authorities feel that any self-regulation would have to be supplemented by legislative regulation. IBEC's standpoint is that the situation is not sufficiently clear for manufacturers and sees the US positive list of claims as a viable option. A Code Committee made-up of food nutritionists as well as industry and consumer–nominated representatives could add new claims subject to review. The burden of proof would be on the manufacturers to substantiate claims they wanted to add to the list.

2. Code of Advertising Standard for Ireland

Of interest is also the Code of Advertising Standard for Ireland, established by the independent self-regulatory body of the Advertising Standards Authority for Ireland (ASAI). The Code covers all means of communication equally and there are specific rules to cover health, beauty, slimming and environmental claims. The code comprises a well-defined complaint procedure; sanctions; and a pre-publication vetting service, which according to the ASAI, was an invaluable system as many possibly misleading claims were pre-vetted and dropped before ever being aired.

Interestingly, the authorities expressed reservations about self-regulation and voluntary instruments in the case of health claims. They believe that the regulators should be involved, as, for example, the ASAI code does not offer sufficient consumer protection as it functions in a passive way, not going out of its way to verify

possible misleading advertisements. There is also concern that there is a lack of consumer awareness of the complaint procedure, to the extent that it was generally acknowledged that there is a lack of any real tradition of making formal complaints in Ireland. This is, however, changing as awareness of general food safety and health issues is growing and, hence, consumer demands for controls will be made sooner rather than later.

3. Ethical Claims

With regard to ethical claims, there are two types of initiatives: the campaign by companies and retailers to promote good commercial practice/guaranteeing certain minimum conditions for workers and the introduction of products trading under an ethical label.

These company campaigns, which focus primarily on the banana, toy and supermarket sectors, are highly commendable but there is always the fear that the members of these codes might use them as a basis of ethical claims in promotional activities. While the codes of conduct issue is implicitly linked to the issue of ethical claims, it is important to note that no supermarket or company in Ireland is using a code of conduct as a basis to make ethical claims about its products. In fact, there has been widespread reticence about using codes of conduct as a marketing tool. This is in contrast to fairtrade labels, which have been used as the basis for marketing campaigns and the use of ethical claims.

Products trading under a fair trade label have begun to gain a hold on the Irish market. The label is awarded by the Irish Fair Trade Network (IFTN), which is a member of a pan-European organisation, the Fairtrade Labelling Organisations International, which operates a comprehensive and thorough verification system of all its members. The initiative is still in the early days and, thus, there is no widespread use of ethical claims used by the manufacturers subscribed to the Fair Trade scheme. To date, there have been no verification systems set up by the Irish authorities to check the claims in relation to products bearing the fairtrade label. Nevertheless, as these labels proliferate, the authorities and or consumer organisations might wish for an independent check as these products might be perceived as "better" by the consumer and, therefore, provide unfair competition. For now, Irish authorities seem satisfied with the control systems set up by the Fair trade Labelling organisations.

D. VERIFICATION SYSTEMS

With regard to the issue of verification of claims, the only criteria which exist are those set out in the law on nutritional claims and by the Fair Trade organisations. However, the Irish Medicines Board has developed criteria for medicinal (health) claims, which require that a medical product should have a demonstrable therapeutic benefit. However, the IMB does not provide further information on how a manufacturer would demonstrate a therapeutic benefit in order to substantiate a health claim.

The practice of pre-vetting a claim is hardly used, although it is starting in a very informal way. It is also generally believed that with the proliferation of borderline products, pre-vetting will take place more often and would most probably be carried

out by the FSAI. Interestingly, the ASAI pre-vetting system, which establishes a voluntary, non-binding system, offering no guarantees, is being used a lot by the media and even some manufacturers.

As to post-clearance, it is the eight regional Health Boards, which are responsible for the enforcement of the nutritional claims. They routinely carry out checks. Also, the FSAI, which will take over responsibility for many areas of labelling, including nutritional claims plans to issue Guidance Notes to the eight Health Boards as part of their new service contracts. These Guidance Notes should include one on nutritional labelling and might cover verification guidelines for nutritional claims. The IMB is responsible for medicinal claims and would, therefore, in theory have some responsibility for health claims.

It is the regional health boards and the Director of Consumer Affairs whose job it is to take legal action against manufacturers. The burden of proof also lies with them to prove that on the balance of probability a claim is false. Penalties can range from small fines to imprisonment. In the past five years, there have been no legal cases relating to claims.

E. MEANS OF COMMUNICATION

There is no differences between the means of communication, although the Internet, whilst not proving to be an actual problem yet, was nevertheless earmarked as a potentially huge problem, with no apparent solution to combat misleading claims.

F. CONSUMER PROTECTION

As regards the issue of whether the situation on claims was leading to a lack of consumer protection, both the FSAI and the Consumers Association of Ireland (CAI), agreed that there was a definite lack of consumer awareness about claims. It was found that consumers bought products based on the claims made, rather than on the factual ingredients labelling. Whilst neither could provide concrete examples of consumer complaints against claims (in fact there have been none brought to the Office of the Director of Consumer Affairs in the last 20 years) both agreed that something needed to be done. The former recommended that the European Commission launch an information campaign, providing assistance to the Member States. The latter confirmed their wish to see further regulation on health claims, e.g., a positive or negative list and that the authorities, whether local, national or European, should be more active in prosecuting on misleading claims.

G. BARRIERS TO TRADE

As to barriers to trade within the EU, this seems almost a non-issue in Ireland, save for the fact that there are concerns with regard to the UK Joint Health Claim Initiative, which could establish different norms and/or criteria to that of EU/national Irish implementing legislation and in effect, establish some sort of barrier to trade. Nevertheless, the Irish appear to support the UK initiative. There was mention of trade problems with the US, where clearly their labelling/claims rules were far more liberal and could/will cause problems with foodstuffs entering the market, and via Internet shopping.

H. CASE LAW

No examples of cases in public law have been found over the past five years, although in the **Self-Regulatory Code of the Advertising Standards Authority of Ireland (ASAI)** have examined several cases.

I. STAKEHOLDER ANALYSIS

In general, the Irish authorities tend to look to the UK for the lead on the regulation of many issues, such as nutritional, health and ethical claims, for instance. Irish authorities, including industry and consumers, are closely following developments in the UK with the Joint Health Claims Initiative. As this initiative develops, it is likely that Irish authorities will be under increasing pressure from manufacturers and consumers to regulate on the claims issue and perhaps to follow the same path as the UK.

In conclusion, the positions of the main stakeholders are:

1. Government Authorities

- On nutritional claims, government/FSAI see no need for review.

- On health claims, they wish to see clarification on borderline products (the Irish Medicines Board has already tried to address the issue) and would welcome EU initiative regarding a positive list of health claims, based on sound science, and shifting the burden of proof on the manufacturer. However, amending the Misleading Advertising Directive was not seen as the feasible way forward.

- On ethical claims, there is no real position, although independent checks might be considered in due course.

- The Irish authorities and the various enforcement bodies admitted a lack of resources and, therefore would welcome increased EU involvement. The proliferation of borderline products is a cause of concern, which led them to state that increased pre-vetting would be required.

2. Consumers

- Consumer perception of the issue is only starting to raise questions. The Consumers Association of Ireland indicates the lack of consumer awareness to labelling and claims and, therefore, calls upon the EU to launch an information campaign to assist Member States.

3. Industry

- On nutritional claims, the Irish Business Employers Confederation believes legislation to be unclear and, therefore, request amending clarifications.

- On health claims, the IBEC also seeks clarification and would promote self-regulation, as in the case of the UK JHCI, with a positive/generic list of allowed health claims, together with a Code Committee to regulate new innovative claims

- On ethical claims, there is no position, except for those organisations which promote ethical trading and who are naturally in favour of voluntary systems.

In conclusion, we would surmise that the Irish situation could require EU action. In particular with regard to health claims and the borderline cases as well as additional clarification for manufacturers on nutritional claims, and finally further checks and balances on the use of ethical codes and claims to ensure that consumer safety and awareness is guaranteed.

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II. MEMBER STATE POLICY

A. DEFINITIONS OF CLAIMS

1. Nutritional Claims

a. Irish definition

In Ireland, the Nutritional Labelling Directive 90/496 is transposed by the Health (Nutritional Labelling for Foodstuffs) Regulations, Statutory Instrument No. 388 of 1993 (Annex 1). These Regulations provide the definition of a nutritional claim as "any representation and advertising message which states, suggests or implies that a foodstuff has particular nutrition properties due to the energy (calorific) value it

- provides,
- provides at a reduced or increased rate, or
- does not provide,

and/or due to the nutrients it

- contains,
- contains in reduced or increased proportions, or
- does not contain."

b. EC definition

The Irish definition is word for word the same definition as the Directive 90/496.

c. Codex Alimentarius definition

The Irish definition is stricter in terms than the Codex definition. While both the Irish definition and the Codex allow nutrient content claims, comparative claims, and nutrient function claims, claims related to dietary guidelines or healthy diets are not allowed by the Irish definition.

2. Health Claims

a. Irish definition

Directive 79/112 on the Labelling, Presentation and Advertising of Foodstuffs is transposed in Ireland by the S/I 82/205 European Communities (Labelling, Presentation & Advertising of Foodstuffs) Regulations, 1982 (attached in annex 2).[17]

[17] Explanatory Note: A number of different methods are used to implement EU directives in Ireland. Primary legislation is occasionally used but more generally secondary legislation (statutory instruments or S.I.s) is used. Secondary legislation can, in turn, take a number of forms, including restating the text of the Directive in the S.I. (as is the case with SI 388/93 implementing Directive 90/496) or implementation of the directive "by reference" (as is the case with SI 205/82). That is to say, the S.I. simply states (as does Regulation 5(1) of S.I. 205 of 1982) that "A person shall not sell foodstuffs unless they comply with the provisions of the Council Directive [79/112/EEC] and these Regulations". The rest of the S.I. consists of exemptions, derogations and ancillary provisions such as the power to prosecute.

Thus, following the wording of Directive 79/112, health/medicinal claims for a foodstuff are defined as 'attributing to that food the property of preventing, treating or curing a human disease'. The reference to a disease in a claim would put that claim in the health/medicinal category and it would thus be examined by the Irish Medical Board (IMB) (see further on the IMB below). Claims should not mislead consumers and it prohibits such claims (in labelling, presentation or advertising) relating to the prevention, treatment of cure of disease.

In Ireland, products containing vitamins and/or mineral ingredients, herbal ingredients and/or amino acids and whose labelling or accompanying or associated literature make any preventative, curative or remedial claim or whose recommended daily intake exceeds the maximum recommended allowance for such constituent are regarded as medical preparations and must receive approval as such to be placed on the market.

b. EC definition

The Irish definition follows the EC definition word for word.

3. Ethical Claims

There is no definition of an ethical claim in Irish legislation.

B. LEGISLATION IN PLACE

1. Nutritional Claims

In Ireland, the Nutritional Labelling Directive 90/496 is transposed by the Health (Nutritional Labelling for Foodstuffs) Regulations, Statutory Instrument No. 388 of 1993 (Annex 1).

The Health Regulation follows the wording of each article of the Directive, with the exception that Article 2 of the Directive is not included i.e. "Subject to paragraph 2, nutrition labelling shall be optional. Where a nutrition claim appears on labelling, in presentation or in advertising, with the exclusion of generic advertising, nutrition labelling shall be compulsory".

2. Health Claims

Directive 79/112 on the Labelling, Presentation and Advertising of Foodstuffs is transposed in Ireland by the S/I 82/205 European Communities (Labelling, Presentation & Advertising of Foodstuffs) Regulations, 1982. The wording of the Directive is followed exactly by the Irish legislation, with a health claim for a foodstuff defined as 'attributing to that food the property of preventing, treating or curing a human disease'.

3. Ethical Claims

There is no legislation in place dealing with ethical claims.

C. EXISTING PROHIBITIONS, RESTRICTIONS AND EXEMPTIONS

1. Nutritional Claims

As per Directive 90/496, SI 388 of 1993 states in Article 2 that "these Regulations shall not apply to:

(i) natural mineral waters or other waters intended for human consumption,
(ii) diet integrators, or
(iii) food supplements."

2. Health Claims

All health claims are banned in Ireland without exemption.

3. Ethical Claims

Not applicable as there is no Irish legislation on ethical claims.

D. POLICY DEVELOPMENTS AND STAKEHOLDERS' POSITIONS

No major policy changes are envisaged by the Irish government on the issue of claims, although some minor developments will take place with:

(a) the transposition into Irish law of:

- Directive 97/36/EC amending Directive 89/552/EEC on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the pursuit of television broadcasting activities, and
- Directive 97/4/EC amendment Directive 79/112/EEC on the approximation of the laws of Member States relating to the labelling, presentation and advertising of foodstuffs; and

(b) The FSAI, which is still in the process of being formally set-up, will issue service contracts to the eight regional Health Boards in Ireland. As part of these service contracts, the FSAI plans to issue Guidance Notes on a number of issues, among them nutritional labelling. The FSAI official mentioned that they intended to use the Swedish guidance note as a model.

1. Nutritional Claims

It is generally felt by Irish administrators that the legislation on nutritional claims is quite clear and they have found no problems in relation to nutritional claims.

Officials we spoke to expressed their concern that this study would lead to the setting up of another working group, this time on the issue of health claims, as had happened following the study on environmental claims. These working groups, involving all interested parties such as Member States, consumers, NGOs, industry, were ineffective talking shops and concern was expressed about their proliferation. Groups

of national representatives were much more effective and, in any case, were always balanced by inter-service consultations within the European Commission.

However, the industry representatives from the Irish Business Employers Confederation felt that the regulation of nutritional claims was far from clear. While nutritional claims are allowed, there are no guidelines for Irish industry on what exactly could be used. As a result, a lot of misinformation was being given out by many manufacturers on the subject of nutrients, such as 'reduced fat' or 'lower cholesterol' comparisons. IBEC was aware that the European Breakfast Association had produced some guidelines for nutritional claims on cereal products.

As stated above, government officials feel that legislation on nutritional claims is well defined and well implemented, with sufficient protection of the consumer. The official from the Food Safety Authority of Ireland (FSAI) agreed with this.

As Ireland follows strictly EC legislation on nutritional claims, there was no trade barriers created with respect to other EU countries. There may, however, be problems in relation to the US. So far, the Irish government has not seen any serious complaint made on this issue. There has, however, been some limited lobbying from a number of US and EU cereal companies to allow a generic list of health claims to be used in Ireland.

2. Health Claims

Health claims, as defined above, are banned in Ireland. Nevertheless, Irish officials recognised that there may be claims being used on labelling and in advertising in Ireland that may constitute health claims. However, they have neither the human nor financial resources to bring manufacturers to court.

The Irish Medicines Board (IMB) [18], on the other hand, has looked at how to address health claims and the many so-called 'borderline' products on the market in Ireland. To clarify the situation regarding these products, the IMB issued a set of guidelines on the definition of a medicinal product (attached in annex 3).[19]

These guidelines describe IMB policy in categorisation of medicinal products for human use. They address those products, which occupy the 'borderline' position between medicines and nutritional products, between medicines and cosmetic substances between medicines and medical devices and between medicines and so-called 'lifestyle' products.

[18] The Irish Medicines Board was established by the Irish Medicines Board Act in 1995. The IMB is the competent authority for the licensing and supervision of human and veterinary medicines in Ireland. The mission of the IMB is to protect and enhance public health and animal health through the regulation of human and veterinary medicinal products. The IMB regulates the manufacture, importation, distribution and supply of medicinal products for human use in Ireland. Under the terms of the Irish Medicines Board Act 1995, anyone who contravenes a regulation made by the Minister under the Act, is liable to fines or to a prison term, as appropriate. The IMB regulates the licensing and sale of medicinal products for human use in Ireland by means of the medicinal Products (Licensing and Sale) Regulations (S.I. 142 of 1998) (Regulations) and relevant EC Directives.

[19] The IMB stresses that these guidelines should not be assumed to be a definition of the law in this area and that they should be read in conjunction wit the various relevant Directives and Regulations.

The IMB states that the interests of medicine users should be protected in a number of areas, in particular regarding claims. The guidelines state that 'there should be demonstrable therapeutic benefit." If a medicinal claim is made, the consumer is entitled, within reason, to expect a benefit and the review process should protect the consumer, as far as possible, from products which do not offer a potential for such benefit. (Page 4)

With this in mind, the IMB goes on to define a medicinal product. As part of the presentation, the IMB examines the totality of the product including products for which (explicitly or implicitly) claim to cure, alleviate or prevent disease. These products will be considered by the IMB as medicinal products. Any particular words or phrases, which imply such a claim, will be taken into account (page 5).

The IMB then provides a list, not intending to be exhaustive, of words or phrases which could imply a claim: cures, heals, treats, restores, prevents, clears, stops, protects, helps with, traditionally used for, strengthens the immune system, calm, helps maintain normal water balance.

The IMB takes into account the ECJ judgement from 1991 (OJ 1991 C219, 91 attached in annex 4) which states that a product which is recommended or described as having preventive or curative properties is a medicinal product … even if it is generally considered as a foodstuff and even if it has no known therapeutic effect in the present state of scientific knowledge.

The IMB in its guidelines addresses 'borderline' products in four particular areas, namely cosmetic products, foods, herbals and slimming products. In relation to foods, the IMB states that clearly most foods are not medicinal products. There are, however, certain products that may be classified as medicinal products even in circumstances where they may be described by the manufacturers as 'foods' or 'food supplements'. In this regard, the IMB clearly has in mind products which are presented in a form usually associated with medicinal products, i.e. capsules, tablets or certain liquids, rather than more regular foodstuffs. The IMB's position on those products is nonetheless relevant. For the subcategories of foods which the IMB examines, products containing vitamins and/or minerals, and products containing selected amino acids, it states that these preparations are considered to be medicinal products when their labelling or associated literature makes any preventative, curative or remedial claim (page 10).

Having thus defined a medicinal product, the IMB states clearly that unless a specific exemption has been granted, medicinal products may not be marketed without a current product authorisation in accordance with the 1998 regulations. It is the responsibility of the person or organisation marketing such a product to ensure that the relevant legislation is complied with. Failure to comply with this legislation may result in prosecution, with liability for fines or prison terms (page 16).

After discussions with the Food Safety Authority of Ireland (FSAI)[20], we gather that such guidelines on borderline products should be issued at EU level under Directive

[20] The Food Safety Authority of Ireland came into being in January 1999. It is a statutory, independent and science-based body, overseeing all functions relating to the regulation of the food industry. In July 1998, the Food Safety Authority of Ireland Act was passed, providing for the FSAI to take over all the

65/65 on medicinal products. As a further step, a positive list of health claims should be developed at EU level. A positive list of claims should be made, rather than a nebulous set of guidelines or definitions. That way the burden of proof would be on any manufacturer who wanted to add a claim to the list and a Scientific Committee would consider the evidence put forward. National Authorities (or European authorities) could then prosecute on the basis of this list without having to mount a huge scientific case.

It was suggested that the Novel Foods Directive, which for the first time provided for a pre-market assessment for products not significantly used in the EU, might be a way forward to pre-vet claims.

The Department of Enterprise, Trade and Employment suggested that the Misleading Advertising Directive would not be the best way forward on the health claims issue. He felt that the issue was too complex for a broad-based Directive such as this and that it would be better dealt with sectorally.

The Food Safety Authority of Ireland (FSAI) felt that manufacturers should be allowed to give information about certain properties of their product, specifically on the issue of trans-fatty acids. Manufactures, the FSAI felt, should be allowed to give information to consumer about their benefits. There also seemed to be strong views about the need to be clearer rules on health claims, such as providing a positive list of claims firmly based on sound science, as developed by the FDA in the US. The real benefit of such a list would be to place the burden of proof with the manufacturer who wanted to add a claim to the list. It was suggested that an EU Scientific Committee could be responsible for adjudicating on claims.

The DETE and the Department of Health did not feel that there was any real lack of consumer protection in relation to health claims. They pointed to the lack of any consumer complaints against claims. There have been no complaints on the issue over the 20 years of the existence of the Office of the Director of Consumer Affairs (ODCA) [21]. In any case, Irish government officials felt that Irish consumers were

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regulatory functions of existing authorities (relevant government Departments, Health Boards, Local Authorities etc.) The principle function of the FSAI is take all reasonable steps to ensure that food produced, distributed or marketed in the Republic meets the highest standards of food safety and hygiene reasonably available. The FSAI also ensures that food complies with legal requirements, or where appropriate, with recognised codes of good practice. The FSAI comes under the aegis of the Minister for Health and Children and currently has a board of five. It also have a 15 member Scientific Committee that assists and advises the Board.
In August 1999 the new Food Safety Law came into force and the FSAI formally took over responsibility for 48 food law enforcement agencies, including the regional Health Boards. The new Authority will operate on the national food safety compliance programme by means of service contracts with these agencies. In future, these agencies will act as agents of the Authority in the performance of their contracts and the Authority will publish details of these contracts. The contracts will come into effect by the end of 1999 and will apply for 3½ years with reviews at the end of each year. The FSAI also acts as an information resource, operating a Food Safety helpline and a Food Safety Information Centre. More information about the FSAI, as well as some of the information brochures it has produced, is attached in annex 14.

[21] The current Director of Consumer Affairs is Carmel Foley, appointed in November 1998. The post was created in 1978 to make criminal law prosecutions against offences of making false or misleading statements about goods or services, a remit which has now been extended to cover many other consumer rights. The DCA now has responsibilities for over 60 regulatory measures. The Director's office also takes care of small consumer claims (where the consumer does not necessarily have to use a

quite sceptical about the claims made by manufacturers. The Irish Advertising Standards Authority (see below) also shared this view.

The Food Safety Authority of Ireland (FSAI), however, felt that there was a lack of protection. This was due to the lack of consumer information about claims. This is in fact one of the jobs of the new FSAI to increase consumer awareness about claims and to launch an information campaign on the issue. It was suggested that this was an area where the European Commission could be of great assistance to Member State governments, by providing materials to help create awareness about claims.

The Consumers Association of Ireland (CAI) also feel that there is a lack of consumer protection on health claims, as they pointed out that most consumers base their buying decisions on the claims made by producers rather than the factual information on the product label.

The CAI feels that a positive and negative list of health claims would be a good way to address the lack of consumer protection. According to the CAI, the positive list must have strict definitions and criteria for making these claims. An expert committee should have responsibility for advising on, and monitoring, the issue of these claims.

It was suggested that the burden of proof should not be left solely up to manufacturers, as substantiating information they put forward is often not reliable. The CAI believes that the authorities, Irish or European, should take a more active rule in prosecuting on misleading health claims. Overall, the CAI called for a new Directive, specifically dealing with both nutrition and health.

Again, as Irish legislation follows EC legislation on health claims, there are no barriers to trade created by the fact that Ireland does not allow health claims. Government officials had no examples from industry about barriers to trade. However, officials pointed out that should, for instance, the UK set up guidelines, referring to the Joint Health Claims Initiative (see UK Country Section), there is no doubt that this might cause a legal barrier to trade. In such a case, Irish legislation would most likely be adapted to follow UK rules.

3. Ethical Claims

The issue of ethical claims is not a very important one for the Irish authorities we spoke to. There has been little response from the Irish government to NGO and Trade Union activity on the issue of codes of conduct for multinational companies or to initiatives such as the Fairtrade label.

The Irish government does, however, provide indirectly some funding for NGO campaigns through the National Committee for Development Education. This funding is given on the basis of an annual application round for grants to be used for development education (i.e. education about "Third World" issues). The total amount allocated is about IEP 1 million. The total amount allocated to work on codes of

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solicitor or other legal advisor to seek redress) and runs a Consumer Helpline. The Director of Consumer Affairs (DCA) is independent from the government but her office is staffed by government officials. The DCA's Annual Report for 1998 is attached in annex 15.

conduct was given to the Irish Free Trade Network (IFTN- see more below), and amounted to about IEP 3,000 in 1998. An additional IEP 40,000-50,000 was allocated to three of four organisations working on 'fair trade'.

At a recent conference entitled ('Ethical Trading Initiative – Ireland' on 23 April 1999) the Minister for Labour, Mr. Tom Kitt, welcomed initiatives to increase awareness about the problem of working conditions and expressed the hope that Irish companies would adopt codes of conduct. However, he did not mention any role for the Irish government in this process (speech in annex 5).

III. VOLUNTARY INSTRUMENTS AND OTHER PRACTICES

A. VOLUNTARY INSTRUMENTS IN PLACE

1. Code of Advertising Standards for Ireland

The main voluntary instrument in place in Ireland dealing with any type of claims is the **Code of Advertising Standards for Ireland of the Advertising Standards Authority for Ireland (ASAI).** It is the independent self-regulatory body set up and financed by the advertising industry. The rules are set out in the Code of Advertising Standards and the Code of Sales Promotion Practice, drawn up by the Board of ASAI following consultation with relevant interests including consumer representatives and Government Departments (a copy of the ASAI is attached in annex 6).

The Code of Advertising Standards applies to commercial advertisements, i.e. those which promote the sale of a product or service. The Code defines an advertisement as a paid-for communication addressed to the public or a section of it. It is characteristic of an advertisement that the advertiser engages media to communicate a commercial message. In effect the ASAI code covers all means of communication equally.

The Code contains a set of General Rules and these are supplemented by additional requirements for particular products or sectors. These sectors include health and beauty, slimming and environmental claims.

The complaints procedure against any advertisement is as follows: The complaint is evaluated initially by the Secretariat to determine whether it is within the terms of reference of ASAI and whether there is a case for investigation. Where there is a case to answer, the advertiser or promoter (or the agency involved) is informed of the complaint and invited to comment. In the light of the response, the Secretariat prepares a recommendation to the Complaints Committee and sends a copy to the complainant and the advertiser who have an opportunity to express further views in the matter before adjudication.

The ASAI Complaints Committee decides whether or not Code rules have been contravened. Details of the case, including the names of the advertiser and the advertising agency involved, together with the Committee's adjudication, are set out in a Case Report which is issued to the parties involved and released for publication. An advertisement or promotion which breaks the rules must be withdrawn or promptly amended.

The Complaints Committee comprises five persons who are professionally involved in the advertising business and eight independent members including four nominees of the Director of Consumer Affairs.

Publication of Case Reports, including names of advertisers and agencies involved, is an important element of the self-regulatory system. An advertisement or sales promotion which breaks the rules must be withdrawn or amended and media will refuse to publish an advertisement which fails to conform to Code requirements.

A member who does not accept ASAI decisions may be disciplined by the Board and may be subject to penalties including fines and/or suspension of membership. These penalties are rarely invoked; there is a strong commitment to the self-regulatory system throughout the advertising business and ASAI adjudications are invariably accepted and implemented.

There also exists a pre-publication vetting service, which is available free of charge. The advice given is not binding and there is no guarantee that there will not be any problems with the advertisement or campaign when run.

2. Irish Business Employers Confederation

In Ireland there has been some attempt by industry to start up an initiative along the lines of the Joint Health Claims Initiative in the UK. In June 1998, the **Irish Business Employers Confederation** (IBEC) held a meeting of interested parties on the issue of claims. It included representatives from Goldenvale (an Irish manufacturer of margarine spread), Kellogg's, Nestlé, as well as nutritionists from the FSAI, government officials, and a representative from the Director of Consumer Affairs. Since that meeting little was done, due to a lack of time and resources, but IBEC mentioned that it hoped to take the issue up again over the coming months. IBEC is hoping that the government authorities, such as the FSAI, will support them in their moves towards self-regulation.

IBEC's approach to health claims is that they have found that consumers want to be given the type of information that claims provide. That is to say, consumers want a link to be made between a product and the health effects it can have. Simply listing the ingredients of a product means very little to most consumers. In that context, Irish industry feels that it should be allowed to make health claims.

IBEC's position is that companies need clear guidelines on what claims are and on what is not allowed. IBEC also suggests a list of positive claims, as used in the US. Any new claims to be added to that list would then be subject to peer review, for example, by a Code Committee. This Committee should be science-based, made up of food nutritionists, as well as industry and consumer-nominated representatives. The burden of proof would be on the manufacturers to substantiate claims they wanted to add to the list.

IBEC is closely watching developments in the Joint Health Claims Initiative in the UK and is very positive about that approach. IBEC seemed more in favour of the

guidelines being developed in the UK rather than the work being carried out by the CIAA on claims.

B. DEFINITIONS USED IN THE VOLUNTARY INSTRUMENTS

1. Nutritional Claims

In Section 3.10 of the ASAI Code states in relation to vitamins, mineral and food supplements that "An advertisement should not suggest or imply that a well balanced diets needs to be augmented by vitamins or minerals on a regular basis. Advertisements should not imply that supplements will guard against dietary deficiency, elevate mood or enhance performance and supplements should not be promoted as a substitute for a healthy diet". It goes on " Although there may be some depletion of vitamin stores during illness, an advertisement should not suggest that the replacement of such vitamins will influence the speed or extent of recovery".

2. Health Claims

The ASAI Code contains a Section 3 on Health and Beauty, which refers to the Medicinal Preparations (Advertising) Regulations, 1993 regarding the advertising of medical preparations. The Code states that " claims about health and beauty products and treatments should be backed by substantiation including the results of practical trials on human subjects of sufficient rigour, design and execution as to warrant general acceptance of the results". Furthermore, part 3.5 of the Code states that "An advertisement for a health or beauty product or treatment …. Should not imply words, phrases or illustrations that claim or imply the cure of any ailment, disability, illness or disease, as distinct from the alleviation or relief of symptoms; ..should not suggest that a product or treatment will achieve success in every case or that the outcome can be other than dependent on the particular circumstances of the individual person".

3. Ethical Claims

The ASAI Code makes no special reference to ethical claims, but it is accepted that such claims would fall under verification provisions of the Code.

C. VOLUNTARY INSTRUMENTS ACCEPTED/RECOGNISED BY THE AUTHORITIES

The Office of the Director of Consumer Affairs (ODCA) is responsible for approving self-regulatory codes. Besides the ASAI Code on Advertising, other Codes include the Code of Standards of Advertising for Proprietary Home Medicines of the Irish Pharmaceutical Healthcare Association.

In general, it is important to note that government officials expressed some reservations about self-regulation and voluntary instrument. They felt that the ASAI's code worked because advertising was a very special industry. However, with something as serious as food safety and human health, they felt that public regulators should be involved. This is not an issue that could be regulated without real government involvement. Officials had had some negative experiences with other

self-regulatory codes, which they felt were not being adhered to by industry. Insurance and infant food codes were two examples.

This view was shared by the FSAI, which felt that the ASAI did not in fact offer enough consumer protection as it functions passively, i.e. questions are brought to the ASAI's attention rather than the ASAI actively monitoring advertising. Thus, he felt that the ASAI may be missing certain misleading advertising.

The Consumers Association felt that while the ASAI Code was not ideal, it was perhaps the best way to regulate the advertising sector.

E. OTHER PRACICES

In Ireland, there are currently two types of initiatives related to the issue of ethical claims. The first is the campaign for multinational companies and retailers to adopt codes of conduct and the second is the introduction of products trading under an ethical label into the Irish retail sector.

1. Codes of Conduct

Current campaigns for companies to adopt codes of conduct are relevant to the claims issue, as codes of conduct are the first step towards making manufacturers and, in turn consumers more aware of ethical questions. Once codes of conduct are adopted by a manufacturer or a retailer, they might then be used as the basis for advertising and promotion, leading to ethical claims.

The campaign for the adoption of codes of conduct in Ireland is mainly focussed on three sectors: (i) supermarkets, (ii) the banana trade and (iii) the toy sector.

a. Supermarkets

Regarding supermarkets, this initiative has mainly come about following similar campaigns in the UK. As UK supermarkets, such as Tesco, which also operates in Ireland, have begun to adopt codes of conduct, it is expected that Irish supermarkets will also follow suit.

While many initiatives discourage supermarkets from using their involvement with codes of conduct as a promotional issue, as retailers make a greater commitment to ethical trade and codes of conduct, they will want to use this as a competitive advantage. Supermarkets might then use Codes of Conduct as the basis of ethical claims in promotional activities.

The campaign in Ireland has been focused on supermarkets' own brands, which have a large role in the Irish retail sector, and trying to make supermarkets responsible for the conditions under which they are produced.

However, in the Irish retail sector, there is very little direct buying. Irish supermarkets purchase products through the large European wholesale buying groups. This situation is unlike the UK, where there is a lot of direct buying (i.e. supermarket buys direct from producer/grower). Thus, it has been argued that this lack of direct

links with the supply chain places Irish retailers in a more difficult position than their UK counterparts (see 'Who profit? Who pays?' an analysis of the role of Irish supermarket in ethical trade produced by Christian Aid Ireland, Development Education for Youth (DEFY) and the Irish Fair Trade Network in annex 7). Thus, Christian Aid in its report, states that 'consumer concern' must be harnessed so as 'to provide the grocery retailers with the ammunition to put pressure upon their suppliers' (page 26, 'Who profit? Who pays?' an analysis of the role of Irish supermarket in ethical trade produced by Christian Aid Ireland). Thus, there have been a number of awareness-building campaigns aimed at the Irish consumer on the issue of working conditions. One example has been 'The Great Supermarket Challenge' aimed at raising awareness among school children, run by Christian Aid Ireland and DEFY (in annex 8).

It has also, however, been pointed out that the lack of direct involvement of Irish supermarket chains may make it easier for them to adopt codes of conduct.

To facilitate the adoption of codes, Christian Aid, along with its international partners the Fairtrade Foundations, the International Union of Food and Agricultural Workers, as well as Development Education for Youth (DEFY) and the Irish Fair Trade Network in Ireland, have drawn-up a model code of practice based on ILO Labour Conventions, which they want adopted by Irish supermarkets (in annex 9). This Code of Practice calling on suppliers and retailers to guarantee certain minimum conditions for workers producing the products they supply and sell.

So far, Irish supermarkets have shown a strong interest in the issue, one or two are considering the SA8000 standard, though none have as yet directly adopted a code of conduct. Tesco and Marks and Spencer have adopted the British Ethical Trading Initiative Code, and account for more than 20% of the Irish retail grocery trade.

As part of the campaign for the adoption of codes by supermarkets, an Ethical Trading Seminar was organised in the European Parliament Office on 23 April 1999, with the involvement of Irish NGOs, government officials, politicians, supermarket representatives, industry representatives, and Trade Unions (see attendance list in annex 10). The aim of the seminar was to provide information on codes of conduct, what international standards and what independent verification systems exist, international best practice in codes of conduct and to exchange ideas on codes in Ireland.

b. Banana Trade

The reasons for the Irish interest in the banana trade is that Fyffes is an Irish fruit importing company, with 30 per cent of their sales in bananas and a strong presence in developing countries. As a result of growing pressure from both the UK and Ireland, Fyffes signed up to the UK Banana Industry Code of Best Practice along with other banana importing companies, such as Del Monte and Geest Bananas (see annex 11). This Code commits its signatories to the development of a safe, financially viable and environmentally sustainable banana industry. It has not, up until now, been used as a selling point by the Banana Industry, though may be so used in the future.

c. Toy Industry

The third sector that has attracted interest is the toy sector. In the run up to Christmas 1998, an 'Ethical Shopping Campaign' was launched by Trócaire, an Irish NGO operating in the third world, and the Irish Congress of Trade Unions to urge multinationals to adopt and implement codes of conduct for their suppliers and subcontractors. The campaign was targeted at Mattel and Hasbro in particular.

While the codes of conduct issue is implicitly linked to the issue of ethical claims, it is important to note that no supermarket or company in Ireland is using a code of conduct as a basis to make ethical claims about its products. In fact, there has been widespread reticence about using codes of conduct as a marketing tool. This is in contrast to fairtrade labels, which have been used as the basis for marketing campaigns and the use of ethical claims.

2. Fair Trade

Products trading under a fair trade label have begun to gain a hold on the Irish market, albeit a small but rising percentage of the market. It is expected that total sales of fair trade coffee will amount to about IEP 500,000 (max.) (634,869 euro) in 1999. This is less than 1% of the market, but comes from a figure of almost zero in late 1996, when the first Irish fair trade labelled product (Bewley's Direct) was launched. Most of this so far is in the catering market, and retail sales are only now beginning to take off. This share compares to an expected average EU market share of about 3% in the next two to three years, according to the Irish Fair Trade Network (IFTN).

In Ireland, this label (of the same design as the UK) is awarded by the Irish Fair Trade Network (IFTN), which is made up of development agencies, research groups, alternative trading organisations and other individuals.

The IFTN is a member of FLO – Fairtrade Labelling Organisations International, based in Bonn, which operates a common verification system for all its members (see brochure in annex 12). This involves a contract for the importers, who must buy either direct from a list of approved coffee farmers or, where quantities are small, as in the Irish case, from a list of approved importers. This whole arrangement is heavily audited and cross-checked to make sure that the amount supplied exactly matches the amount ordered, sold, etc. Order numbers are cross-checked, etc. This is seen as critical to credibility of the scheme.

In Ireland, Bewleys, an Irish coffee company, was the first to be awarded the Fairtrade label for its fairtrade brand, Bewley's Direct. Two other coffee companies, Robert Roberts and Johnson Brothers (in Northern Ireland) as well as a number of Irish supermarket chains, such as Superquinn, Tesco and Dunnes Stores, now also offer a brand with the fairtrade label. Bewley's Direct has in fact taken a strong hold on the catering market in Ireland, supplying coffee for many universities and large companies.

Bewley's Direct has been marketed and advertised to a certain extent in Ireland. In this advertising, ethical claims have been made. However, in general, fairtrade brands lack the marketing budget of the other larger brands of coffee and so often find it hard

to compete for shelf space in Irish supermarkets. Marketing support has been achieved through publicity in Irish newspapers (see article by Mary Russell in the Irish Times, 19 January 1999 in annex 13). Thus, there is no widespread use of ethical claims by these brands.

In Ireland, there have been no verification systems set up by the Irish government or any other independent bodies to check the claims made in relation to products bearing the fairtrade label. There have been no moves by the Irish government to intervene in the FLO verification system in place.

F. REMARKS ABOUT BARRIERS TO TRADE AND LACK OF CONSUMER PROTECTION

1. Barriers to Trade

In terms of barriers to trade, the ASAI felt that all advertising restrictions were barriers (such as commercial communications differences etc). However, on advertising, officials at the ASAI did not know of any case where an advertisement was allowed in one country but not in another. Of course, there were differences regarding taste and decency, and this is where self-regulation adds value, but not generally on health claims. In this respect, Ireland is at the tail-end of any advertising vetting, i.e. an advertisement is run somewhere else before it is used in Ireland.

2. Lack of Consumer Protection

The ASAI felt strongly that its code offered full consumer protection. That said, officials from the government and the FSAI expressed some reservations about the ASAI's method of vetting, which they suggested may be too passive and may be allowing some claims to be used in advertising that should not be.

It was also suggested that there is a lack of consumer complaints on the issue of claims due to the lack of consumer awareness of complaints processes such as the ASAI. If consumers did have questions or complaints about claims they may not know where to bring them. Some advertisers we spoke to put this down to a lack of any real tradition of making formal complaints in Ireland. The Consumers Association agreed with this assessment.

In general, the ASAI feels that under the current system, both the national legislation and the ASAI code work effectively, and thus does not need to be further regulated at EU level. If there had to be legislation, the ASAI would prefer to see general principles or a general framework rather than any kind of list of claims. It was strongly felt that the EU should look more at what could be done through self-regulation before trying to bring in legislation. Self-regulation had a lot to offer, particularly as it was cheaper, and thus more accessible. It was also more flexible for the consumer to change and modify than legislation. The ASAI suggested that there was no better option on advertising than self-regulation.

IV. VERIFICATION SYSTEMS

A. CRITERIA FOR SUBSTANTIATING CLAIMS

1. Nutritional Claims

There is no list of criteria for substantiating nutritional claims, other than the information provided in the Nutritional Labelling Directive 90/496, as transposed by the Health (Nutritional Labelling for Foodstuffs) Regulations, Statutory Instrument No. 388 of 1993.

2. Health Claims

There is no list of criteria for substantiating health claims in Irish legislation.

The Irish Medicines Board states that any product making a health claim would be seen as a medicinal product and would require IMB authorisation for use in Ireland. One of the IMB's requirements of a medicinal product is that there should be a demonstrable therapeutic benefit. If a medicinal or health claim is made the consumer is entitled, within reason, to expect a benefit and the review process of the IMB should protect the consumer, so far as possible, from products which do not offer a potential for such benefit.

The IMB does not give any further detail on how a manufacturer would demonstrate a therapeutic benefit in order to substantiate a health claim.

3. Ethical Claims

There is no list of criteria for substantiating ethical claims in Irish legislation.

B. LEGAL/ADMINISTRATIVE SYSTEMS FOR VERIFYING CLAIMS

1. Pre-Clearance Rules/ Guidelines

a. Nutritional Claims

No formal guidelines or rules have been produced for the pre-vetting of nutritional claims on labelling or advertising at government level. Any pre-vetting that does take place at government level is purely informal.

b. Health Claims

As for nutritional claims, no formal guidelines or rules exist for the pre-vetting of health claims. Again, any vetting that does take place is on an informal basis.

It was suggested, however, that with the proliferation of borderline products on the market, the government would be called upon more and more often to give an opinion.

The FSAI felt that this pre-vetting role may fall more and more to the FSAI.

At the self-regulatory level, the ASAI Code carries out a lot of pre-vetting. There are, however, no formal guidelines or rules set down by the ASAI for the pre-vetting of claims. The pre-vetting is entirely voluntary and non-binding. The ASAI offers no guarantee that there will be no problems with any advertisement after it passes pre-vetting. Most of the ASAI's pre-vetting questions come from the media (newspapers, broadcasters etc), though some manufactures do come to the ASAI first.

The advertising industry uses the ASAI a lot, as the industry must be seen as a responsible industry as advertising is based entirely on consumer trust. Generally, pre-vetting lasts one day, as the ASAI was aware that advertisers were under time pressure. The ASAI is currently trying to raise awareness of its activities among the media, industry and consumers. This was beginning to have an effect, as the ASAI pre-vetting facility is being used more and more by manufacturers. It was suggested that this was due to increased awareness of the ASAI rather than manufacturers trying out more controversial advertisements.

The Consumers Association of Ireland mentioned that some manufacturers had approached them to give endorsement to certain products, which they refuse to do, as it is against their policy.

c. Ethical Claims

There is no experience in the Irish government of any pre-vetting, formally or informally, of ethical claims.

2. Post-Clearance Rules/ Guidelines

a. Nutritional Claims

The verification of a nutritional claim is the responsibility of the eight regional Health Boards of Ireland, who enforce S.I. 388/93. No guidelines have been produced by the Department of Health or the Health Boards on their system of verifying nutritional claims, other than the information provided in the Nutritional Labelling Directive 90/496, as transposed by the Health (Nutritional Labelling for Foodstuffs) Regulations, Statutory Instrument No. 388 of 1993. The Health Boards use the control systems in place under the general Health Regulations to control nutritional claims. These involve routine and ad hoc inspections by officers of the Health Boards.

As already mentioned, however, the FSAI, which will take over responsibility for many areas of labelling, including nutritional claims, plans to issue Guidance Notes to the eight Health Boards a part of their new service contracts. These Guidance Notes should include one on nutritional labelling and might cover verification guidelines for nutritional claims.

b. Health Claims

Given that health claims are not allowed under Irish law, there are no guidelines or systems in place for the verification of claims.

Taking the IMB approach, a product making a health claim would be controlled in the same way as a medicinal product. Under existing IMB rules, there is a responsibility on the holders of product authorisations to keep the IMB informed of events with potential safety consequences for their products. The Irish Medicines Board also monitors the quality of medicines by conducting inspections at sites of manufacture and distribution of medicines and by random sampling of products both pre and post authorisation.

C. LEGAL PERSONS ENTITLED TO TAKE LEGAL ACTION

1. Nutritional Claims

The eight regional Health Boards in Ireland enforce legislation on nutritional claims. An offence under the Health Regulations may be prosecuted by a health board within the functional area of which the offence was committed (Article 13 of S.I. No. 388 of 1993, the Health (Nutritional Labelling for Foodstuffs) Regulations, 1993).

2. Health Claims

An offence under SI 82/205 which implements Directive 79/112 may be prosecuted by the Director of Consumer Affairs or by a Health Board in whose functional area an offence was committed.

D. BURDEN OF PROOF

1. Nutritional Claims

In any proceedings for an offence under SI 388/93, the burden of proof lies with the prosecution, which must prove on the balance of probability that a claim is false. Such proceedings are tried as civil actions in the District Court in the area of which the offence was committed.

2. Health Claims

The burden of proof lies with the Director of Consumer Affairs or the Health Board bringing the case, who must prove that a claim being used by a manufacturer is actually a health claim and cannot be allowed.

E. APPLICABLE PENALTIES

1. Nutritional Claims

Persons found guilty of an offence under the Health Regulations are liable to a fine not exceeding IR£1,000 (1,270 euro) at the discretion of the Court, or to imprisonment for a term not exceeding six months, or both.

2. Health Claims

Persons found guilty of an offence under SI 205/82 are liable to a fine not exceeding IEP 800 (1,015 euro) or, at the discretion of the court, to imprisonment for a term not exceeding six months or to both such a fine and such imprisonment.

V. CASE LAW

No examples of cases in public law have been found over the past five years.

In the **Self-Regulatory Code of the Advertising Standards Authority of Ireland (ASAI)** there have been two cases which may be considered relevant to the issue of claims.

The first relates, in fact, to an environmental claim, which is nevertheless an indication of how that ASAI may view a health, nutritional or ethical claim. The complaints were from Earthwatch/Friends of the Earth Ireland, the Green party and a number of individual complainants to the Shell (Pura) Petrol campaign. The complainants considered the claim "Purer air. From Pura Petrol" to be false and misleading. Section 11 of the ASAI Code, which deals with environmental claims, provides that qualified claims and comparisons may be acceptable if advertisers can demonstrate that their product provides for an improvement in environmental terms, either against their competitors' or their own products. The Complaints Committee of the ASAI considered that the advertising claim for purer petrol had been substantiated in that regard.

However, the Committee went on to consider that in some radio advertisements, expressions such as "it's a breath of fresh air …" and "Shell Pura doesn't just help make the air clean .." were tantamount to being absolute claims, which could not be justified and should not be used. The Committee concluded, however, that consumers in general would be well aware that emissions from all petrol engines are harmful to the environment and would not be led to believe that they would result in the environment depicted in the advertisements.

The second complaint related to claims made in advertising by the National Dairy Council (NDC) to the effect that "milk is good for your bones". The complainant said that the entire scientific community connected with nutrition knows that calcium in milk is passed straight out of the body, doing no good whatever. The complainant also contended that milk is actually a major contributory factor to osteoporosis, which is caused by excessive protein and not calcium deficiency. He asserted that these facts have been proven in every study carried out on this subject and quoted studies and references in support of the complaint. The complainant said that the only contradictory studies had been funded by the National Dairy Council of Ireland or its counterparts in other countries.

The complaint was not upheld as the Committee felt that it would be more appropriate for the complainant to pursue the various differences of opinion in a scientific/academic forum.

VI. MEANS OF COMMUNICATION

All those interviewed stressed that there was no difference in the regulation of the means of communication, such as broadcast and print media. In Ireland, regulation of the Internet is still at a very early stage.

VII. STATISTICS ON CLAIMS

No statistics on claims in Ireland are available from any of the sources checked, including the Consumers Association, Industry Confederation, Government officials, Advertising Association, and the Food Safety Association.

VIII. ANNEXES

1. SI 388/93 on Nutritional Labelling
2. SI 210/82 on Presentation, Label23 ling and Advertising of Foodstuffs
3. Irish Medicines Board Guidelines on the Definition of a Medicinal Product May 1999
4. ECJ Case Ter Voort C219/91.
5. Speech by Tom Kitt, Ethical Trading Initiative Ireland, 23 April 1999
6. ASAI Code of Conduct
7. Irish Supermarkets in Ethical Trade, DEFY and IFTN
8. The Great Supermarket Challenge, DEFY and IFTN
9. Model Code of Practice, DEFY and IFTN
10. Ethical Trading Seminar attendance list
11. UK Banana Industry Code of Best Practice
12. FLO information
13. Article by Mary Russell, Irish Times, 19 January 1999
14. FSAI information
15. Annual Report for 1998 of the Director of Consumer Affairs

IX. DATABASE OF CONTACTS

J. ITALY

I. EXECUTIVE ANALYSIS

A. INTRODUCTION

This study on nutritional, health and ethical claims was generally well received by all interested parties in Italy, although we were unable to obtain information from the consumer organisations. Those who participated in the study were pleased that the issue of claims is being taken up by the EU institutions.

B. MEMBER STATE POLICY

1. Nutritional Claims

Italian legislation provides for a definition of nutritional claims, which is identical to the definition used in EU law. The Italian administration is not particularly satisfied with the current working of the system in place for nutritional claims. The authorities would favour a system of preventive control, but nevertheless acknowledge that it would be probably too difficult to administer. This remark also applies for health claims. Industry, on the other hand, seems to be satisfied with current legislation on nutritional claims.

2. Health Claims

With regard to health claims, Italian legislation implements Directive 79/112 nearly word for word. According to the food industry, the authorities interpret health claims very strictly. The use of claims on disease risk reduction is, therefore, not possible under Italian legislation and the use of enhanced function claims as defined under Codex guidelines are very limited.

Due to the growing problem of "borderline" products, i.e. where the distinction between a food product and a medical product is difficult, the Ministry of health has set up a working group made up of nutritional experts to look into this issue. The working group has already established guidelines to categorize these kinds of products. Another working group of the Ministry is currently looking into probiotic foodstuffs.

No legislative initiatives on health claims are currently planned. The authorities consider that the initiative on health claims has to come from the EU level. Industry also indicated that the EU should regulate health claims. Nevertheless, industry was in favour of an amendment of Directive 79/112.

3. Ethical Claims

The Italian Parliament is in the process of adopting a law on the certification of social conformity of products produced without the use of child labour. Neither the food

industry nor the trade confederation believes that such a legislative measure is needed. Under the law, a register will be set up, in which companies can certify not to use child labour in the production of their products. The law foresees that 60 days after its entry into force, the Minister for Industry and Commerce shall adopt a Decree, in order to institute a social conformity label, which would allow the consumer to clearly and rapidly identify the product as being manufactured without child labour. Subscription to the register has to be renewed every three years. A monitoring committee is foreseen under the draft law. This will be composed of officials, consumers, entrepreneurs, retailers and trade unions.

The law foresees that the Antitrust Authority will have the power to decide on complaints brought forward with regard to social labelling.

C. VOLUNTARY CODES OF PRACTICE

An advertising self-regulation code was adopted in 1966 with the creation of the Advertising Self-Regulation Institute. The code is aimed at ensuring correct and lawful communication. Several Chambers of Commerce use the code as a benchmark. The code contains notably rules for advertising of food integrators and dietetic products, which state that advertising shall not induce consumers "to make nutritional mistakes".

D. VERIFICATION SYSTEMS

As to the substantiation of claims for foodstuffs for particular nutritional uses, as well as fortified food and diet integrators, a sample of the label and on request also scientific literature has to be sent to the Ministry of Health when the product is marketed. In addition, the Italian law on misleading advertising foresees that the Antitrust Authority can ask the advertising operator to furnish proofs on the material exactness of the facts contained in the advertising.

No system of pre-clearance exists. The food industry indicated that such a system was far too heavy. Furthermore, a pre-vetting by the Ministry of Health would in the food industry's view not give the producer the certainty of not facing a complaint, as a Ministerial approval of a claim would not limit the judge's power to act upon a complaint. Nevertheless, food producers, often before putting a product on the market, ask the Ministry of Health on an informal basis to check the conformity of the label and the claim made with national legislation.

As to post-clearance, a special branch of the police (Nuclei Anti Sofisticazione) is responsible for food safety and hygiene. Furthermore, on the basis of the misleading advertising law, consumers, competitors and the public administration can bring a case in front of the Antitrust Authority. The burden of proof is with the plaintiff. Nevertheless the Antitrust Authority can ask the person who has commissioned the advertising or its creator to provide proof of the material's accuracy and of the data contained in the advertising.

The penalties can range from 1.2 million liras to 12 million liras for cases judged on the basis of relevant food legislation. For cases that have been brought to the Antitrust Authority, these are judged on the basis of the misleading advertising law,

which foresees that the Antitrust Authority can order a provisional ban of the advertising in case of urgency and/or it can order the complete ban of the advertising. The Antitrust Authority is a collegial organ, which takes its decisions by majority voting (it is composed of 5 members). If an advertising operator does not follow the order of the Antitrust Authority, he can be fined with up to 3 months imprisonment in conjunction with a fine of up to 5 million lira. Decisions of the Antitrust Authority can be contested in an administrative court.

E. MEANS OF COMMUNICATION

There are no differences between means of communication. However, in cases where the Antitrust Authority is called to decide on advertising broadcast on TV or published in the press, it has to ask the advise of the authority responsible for monitoring broadcasting and publishing.

F. CONSUMER PROTECTION

On the issue of consumer protection, we have not been able to obtain any input from consumer associations (see above). Overall, contacted parties indicated due to the strict interpretation of health claims in Italy, there existed no problems in terms of consumer protection.

Statistics of the Antitrust Authority, which is the administrative body responsible for complaints on misleading advertising, indicate that in the period 1992-1997 there have been a growing number of complaints on misleading advertising. For the same period the statistics indicate that with regard to food out of the 42 cases that were analysed by the Authority only 14% were found misleading. Nevertheless, in the field of cosmetic and health care out of the 100 cases analysed, around 70% were found to be misleading.

As regards ethical claims and consumer protection, the Italian Clean Cloth Campaign indicated that it was against the proposed law on the certification of social conformity of products produced without the use of child labour, as it would allow companies to put a label on their products without that any a-priori control of the companies takes place (under the law companies that want to be put on the register have to send a declaration testifying that they do not use child labour). The Italian Clean Cloth Campaign is also against the possibility of certifying just one single product of one company, as consumers may assume that all other products of the same company have also been produced without child labour.

G. BARRIERS TO TRADE

As for barriers to trade, no examples were mentioned where a health claim had been at the basis of a controversy on trade barriers. The food industry indicated that trade barriers may come up where in one EU Member State a self regulating code exists which allows the use of certain health claims. In this case, the importation of this kind of products into the Italian territory could pose problems.

H. CASE LAW

The only case law as such is the decisions that have been taken by the Antitrust Authority. With regard to health claims, the Antitrust Authority has only dealt with a few cases. These seem to indicate that the Authority follows a rather strict interpretation of health claims.

I. STAKEHOLDER ANALYSIS

Italy follows a rather strict interpretation of Directive 79/112 with regard to health claims. Most interestingly, Italy has introduced a notification procedure not only for dietetic foodstuffs, as foreseen under EU law, but also for fortified foods and food supplements, which are those categories of foods where most often health claims are being made. All interviewees seemed to agree that there was a need to regulate health claims at EU level. Italy is also one of the very few EU Member States that is drafting legislation on ethical claims.

In conclusion, the positions of the main stakeholders are:

1. Government Authorities

- On nutritional claims, the authorities see in principle no need for review.

- On health claims, the authorities consider the interdiction of health claims to be an acceptable approach. Eventually a system of pre-vetting should be introduced, although this was considered to be difficult from an administrative point of view.

2. Consumers

- We were not able to gather the opinion of the Italian consumer associations.

3. Industry

- The food industry seems to be quite satisfied with the current legislation on nutritional claims.

- Industry is in favour of liberalising the rules on health claims. This should be done through an amendment of the EU Directive on labelling of foodstuffs. Industry is clearly against pre-vetting.

- On ethical claims, industry is against the proposed law. The Clean Cloth Campaign, although for other reasons, is against the proposed law, as well.

*** * ***

II. MEMBER STATE POLICY

A. DEFINITIONS OF CLAIMS

It may be useful, as a general remark, to point out that the Antitrust Authority, which is the administrative entity in Italy responsible for misleading advertising (see section VI. A) in particular)**,** often uses the English word claim in its decisions, without making use of any Italian translation.

Also the food industry seems keen to use the English expressions health claims and nutritional claims, without making use of any Italian translation.

1. Nutritional Claims

The Italian legislation provides for a definition of nutritional claims, which is identical to the one provided by the EU Directive 90/496/CEE on the labelling of foodstuff and of alimentary products.

According to the Decree No. 77 of 16 February 1993 (see annex 1), a nutritional claim is:

"*a description or an advertising message which states, suggests or implies that a foodstuff has particular nutritional features regarding:*

1) *the energetic value which it furnishes or it furnishes at a reduced or at a majored value or which it does not furnish;*
2) *the nutrients it contains or that it contains in a reduced or a majored proportion or which it does not furnish*".

According to the same Decree, "*the quantitative or qualitative indication of nutrients, when it is required by the existing legislation*", shall not be considered as nutritional claim as defined above.

2. Health Claims

There is no precise definition of what is to be considered as a health claim in Italy. The only definition is a negative one, as the Decree No. 109/92 (see annex 2) implementing the EU Directive 79/112 on foodstuff labelling, presentation and advertising, prohibits any kind of medical claims, and has been used as a benchmark to prohibit also any kind of health claims.

According to Art. 2 of the Decree 109/92:

"*The labelling, the presentation and the advertising of foodstuff […] do not have to be as such as to induce to confer to the product properties which are aimed to prevent, cure or heal human diseases, or mention features which it does not have. With the exception of what has been foreseen by the norms on nutritional labelling, they [the labelling, the presentation and the advertising of foodstuff] do not have to point out particular features when similar products have the same features*".

According to the Italian food industry, this provision has been interpreted very strictly by the Italian Administration. Disease risk reduction claims, as defined under the latest draft Codex recommendations, are not allowed in Italy. The use of enhanced function claims as defined under the draft Codex recommendations seem to be also extremely limited in Italy (see further sections of the report).

3. Ethical Claims

As specific legislation dealing with ethical claims does not exist in Italy, there is no specific definition of an ethical claim.

The draft Act on the certification of social conformity of the goods produced without the use of child labour, which is currently under discussion within the Italian Parliament (see section D. 3.), does not contain definition of what an ethical claim is. However, in that law, reference is made to a specific "social conformity label".

B. LEGISLATION IN PLACE

1. Nutritional Claims

The EU legislation concerning food and foodstuff has been implemented in Italy through various different laws and decrees.

Directive No. 90/496 on the nutritional labelling of foodstuff has been implemented by the Decree No. 77 of 16 February 1993 (see annex 1).

The Directive No. 398/89 on foodstuff for particular uses was implemented by the Italian Decree 111 of 27 January 1992 (see annex 3).

Special norms on sport foodstuff are contained in a Ministerial Circular No. 8 of the Ministry of Health which was adopted on 7 June 1999, and is awaiting official publication (see annex 4).

Furthermore, there are special rules for beer and olive labelling. The Decree of the President of the Republic No. 272 of 30 June 1998 deals with beer (see annex 5) and law No. 313 of 3 August 1998 regulates the labelling of olive oils' bottles (see annex 6).

Finally, the Ministerial Circular of the Ministry of Health No. 5 of 3 April 1998 regulates beverages coming from other EU member States with high content of caffeine (see annex 7).

2. Health Claims

Directive 79/112 on the labelling, the presentation and the advertising of foodstuff, was implemented by the Italian Decree No. 109 of 27 January 1992 (see annex 2).

The Directive on misleading advertising was implemented by the Decree No. 74 of 25 January 1992 (see annex 8).

3. Ethical Claims

There is no Italian piece of legislation, which regulates ethical claims.

C. EXISTING PROHIBITIONS, RESTRICTIONS AND EXEMPTIONS

1. Nutritional Claims

According to the Italian Decree No. 109 of 27 January 1992 as modified by Decree No. 77 of 16 February 1993 implementing Directive 90/496 on nutrition labelling (see annexes 2 and 1):

"*Only the nutritional information which are related to the energetic value and to the nutrients listed in article 3 point A or that belong or compose one of the categories of said nutrients, are allowed".*

The products listed in Article 3 point A are:

1. *Proteins;*
2. *Carbohydrates;*
3. *Fats;*
4. *Food fibres;*
5. *Sodium; and*
6. *Vitamins and mineral salts which are listed in the annex and are present in a significant quantity according to what is foreseen in the annex itself*".

According to the Annex of the Decree 77/93,

"*a quantity is significant for each 100g or 100ml when it represents at least 15% of said portion*".

The main prohibitions, restrictions and exemptions to the use of nutritional claims are contained in the Italian Decree No. 111 of 27 January 1992 (see annex 3), which implements the Directive 398/89 on foodstuff for particular nutritional uses.

According to this Decree, it is possible to use the word "dietetic" or "di regime" only to indicate two specific kinds of products:

a) foodstuff which is aimed at the nutritional needs of those people whose assimilation process or whose metabolism is disturbed;
b) foodstuff which is aimed at the nutritional needs of those people who are in a particular physiological condition, and hence can have particular benefit from the controlled intake of some substances contained in these foodstuffs.

The Italian legislation explicitly states that in the labelling, the presentation and the advertising of foodstuff for normal use, it is forbidden:

a) to use the word "dietitic" or "*di regime*", both as single words and together with other terms;

b) to use any other expression or whatever claim (in Italian it reads "whatever other 'presentation' – *presentazione*, in Italian") which can generate the belief that it is one of the foodstuffs for particular use as defined above.

The Decree No. 111 of 1992 gave the Italian Ministry of Health the task of adopting a Ministerial Decree to indicate the foodstuff for normal use which could however be used for particular nutritional use. In this case, even if it were not a foodstuff for particular nutritional use as defined above, it would be possible to mention these nutritional properties.

Apart from Decree 111/92, there are other pieces of legislation that provide other specific prohibitions or restrictions applicable only to a specific range of products.

According to the Decree No. 272 of 30 June 1998 on beers (see annex 5),

"The use of the term 'birra leggera' or 'birra light'[22] *is reserved to the product with* PLATO *degree included between 5 and 10,5 and with alcohometric volume title superior to 1,2% and not superior to 3,5%".*

2. Health Claims

With reference to foodstuff for particular nutritional uses, the Decree 111/92 (see annex 3) contains a specific Article entitled "Prohibitions and Information", Article 6.

According to this Article,

"*the labelling and the modalities used for its realization, as well as the presentation and the advertising of foodstuff [for particular nutritional uses] shall not either imply characteristics aimed to prevent, cure or heal diseases, or mention such characteristics*".

However, the Ministry of Health can identify those cases in which derogations to this principle are admitted.

However, "*the diffusion of information and of useful recommendations exclusively targeted to qualified personnel in the sectors of the medicine, of the alimentation and of the pharmacology*" is admitted.

As we pointed out in the section regarding the definitions, health claims are not allowed in Italy.

3. Ethical Claims

So far, no legislation on ethical claims has been brought into force.

[22] Light in English in the Italian text.

D. POLICY DEVELOPMENTS AND STAKEHOLDERS' POSITIONS

1. Nutritional Claims

The Italian administration is not particularly satisfied with the current working of the system in place for nutritional claims. Particularly, the lack of a preventive control on the label and on the claim used by the food producer is perceived as a shortcoming, although the Administration acknowledges the fact that the introduction of such a preventive control would certainly lead to a huge amount of work. This remark also applies for health claims.

The food industry seems to be quite satisfied with how the system on nutritional claims has been working so far, and no changes to the current legislation are deemed necessary.

In the case of foodstuff for particular uses, the Italian administration has come up with a number of mandatory labelling indications, i.e. warnings that have to be put on the label. This is the case for sport foodstuffs. However, an extension of this system to all types of foodstuff does not seem to be considered as a viable option for changing the current situation.

A new Ministerial Circular on sport foodstuff has been signed on 7 June 1999, but is still awaiting publication (see annex 4). This Circular deals with different kinds of sport products, fixing not only compositional standards, but also dealing with specific claims which have to be put on the label of each of these products.

For example, for those products which aim at protein integration, the following claims are to be reported on the label:

- *The total contribution of proteins (diet and integrator) shall not be higher than 1,5 g. per day per each kg of the body's weight.*
- *In case of prolonged use (beyond the 6-8 weeks) it is necessary to ask for the doctor's advice.*
- *The product is counter-indicated in cases of renal pathology, hepatic pathology, during pregnancy and below 12 years.*

For those products which aim at integrating amino acids and derivatives, the following claims are to be put on the label:

For the ramified amino-acids and for the *creatina*:

- *In case of prolonged use (beyond 6-8 weeks) it is necessary to ask for the doctor's advice.*
- *The product is counter-indicated in cases of renal pathology, during pregnancy and below 12 years.*

For essential amino-acids and other kinds of amino-acids:

- *In case of prolonged use (beyond 6-8 weeks) it is necessary to ask for the doctor's advice.*
- *The product is counter-indicated in cases of renal pathology, hepatic pathology, during pregnancy and below 12 years.*

2. Health Claims

The use of health claims in Italy is currently forbidden by Italian legislation, which has implemented the Directive on the labelling of foodstuff maintaining the ban on the use of claims, which refer to the possibility for the product to cure or prevent a disease.

This prohibition has been interpreted very strictly by the Italian administration, which has not allowed any claims to be made in relation to any possible human disease.

Within the Italian Ministry of Health, there is currently a working group made up of nutritional experts which is looking at those cases in which it can be difficult to draw a clear distinction between a food product and a medical product.

This working group already came up with guidelines, which can be used to better categorize these kinds of products (we have not been able to obtain a copy of these guidelines).

Another working group is looking at pro-biotic foodstuff, and is expected to come up with a document which could be the basis of an official Ministerial document or which could simply be used for internal reference.

The Ministry of Health considers the interdiction of health claims to be an acceptable approach. On the contrary, not being able to use health claims is one of the major points of concern for the food industry.

According to the food industry, health claims should be as clearly admitted as nutritional claims, and the areas should be regulated by the EU, through an amendment to the Directive on the labelling of foodstuffs.

No new legislation is expected on health claims. Legislation regulating this issue has to be adopted first at EU level and the Italian Legislator is not planning to take any initiative on its own which could then be contradictory to new EU Directive.

3. Ethical Claims

As we have already mentioned, the Italian Parliament is in the process of adopting a law on the certification of social conformity of goods produced without the use of child labour. *Per se*, this demonstrates that at least the Italian Parliament deems it necessary to have a specific piece of legislation regulating this issue.

It seems that neither the food industry nor the trade associations believe that such a legislative measure is really necessary.

The food industry, although not fully aware of parliamentary initiative on ethical claims, did not show particular support for the introduction of this legislation on ethical labels, while the trade confederation was clearly against it.

According to the trade confederation, the introduction of this new ethical label would probably only further confuse the consumer.

On 2 June 1999, the Upper House of the Italian Parliament adopted a proposed Act which aims to establish a "Certification of social conformity of those products realised without making use of minor age work" (see annex 9).

Although this proposed piece of legislation does not specifically refer to ethical claims, it can constitute a development, which is worth noting. As a matter of fact, this law will establish an apposite Register for those firms which can certify that they do not use child labour in the production of their products, and will provide these firms with the right to put a specific label on the package of their products.

The proposed law makes reference to the international conventions and treaties, which protects the rights of minor age people. In particular, reference is made to the International Convention of the Rights of the Child, and to the Convention No. 138 of the International Labor Organisation.

The Law will institute a specific national Register (Albo nazionale) of those goods manufactured without the use of child labour and of the relative producing firms. The aim of the Register is to "*spread the knowledge among Italian consumers of those products commercialised on the national territory for which no child labour is used during the manufacturing phases*".

Within 60 days of the entry into force of this law, the Minister responsible for Industry, Commerce and Handcraft will have to adopt a Decree in order to institute "*a specific social conformity label*", as a logo, " *which manufacturers will be allowed to put on their production or on the packages of their products or on the products themselves*". This label will "*allow the consumer to clearly and rapidly identify the product which has been manufactured without the use of child labour*".

Signing up to the national Register is not mandatory but voluntary.

In order to have the possibility of signing up to this Register, and hence to use this label, the firms will have to make a specific request accompanied by a declaration which can testify that in no phase of the production was child labour used.

It is important to remark that a firm has three different options when deciding to subscribe to the Register:

- It can decide to sign up for a single specific product;
- It can decide to sign up for the firm as a whole;
- It can decide to sign up for all the products manufactured.

The subscription to this Register has to be renewed every three years. In case the firm does not renew its subscription, the specific Monitoring Committee, which is established by the law itself, will delete the product or the firm from the Register.

The Monitoring Committee will be made up of 7 members: one appointed by the Foreign Trade Minister, one by the Industry Minister, one by the Labour Minister. The remaining four would be appointed by the presidency of the Ministers, and one would represent the consumers, one the entrepreneurs, one the retailers and one the trade unions. These members will not receive any form of monetary compensation for carrying out this function.

It is very interesting to note that the proposed law explicitly makes reference to misleading advertising. According to Article 4, "it is forbidden whatever untrue and misleading advertising, together with the use of whatever label or logo which can generate confusion with the label created" by this law.

This means that the general rules applying to misleading advertising are also applied to this specific label. This is particularly important with regard to the power of the Antitrust Authority, which is the administrative authority responsible for all the cases of misleading advertising. As a matter of fact, the Authority will also have the power to decide cases, which refer to the social labelling provided within this proposed piece of legislation.

Once the law is finally approved and has entered into force, the Monitoring Committee will prepare a yearly report on the status of implementation of the law. This report will have to be presented to the Parliament and to the Government by 31 May of each year.

It is important to note that the Italian centre adhering to the so-called Clean Cloth Campaign does not agree with this proposed legislation. Particularly, the Italian Clean Cloth Campaign is against the possibility provided by the law to certify just one single product of one company, as consumers may assume that all other products of the same company have also been produced without child labour.

Moreover, the fact that signing up to this Register is automatic upon the request of the company, i.e. that there is no a priori control, is perceived as not giving enough security in terms of minor workers' protection. As a matter of fact, the Clean Clothes Campaign has a different proposal, which would allow companies to put a label on their products only after a specific control had taken place. They believe that this procedure would grant a higher level of certainty that no child labour is involved in the manufacturing of a specific product.

E. REMARKS ABOUT BARRIERS TO TRADE AND LACK OF CONSUMER PROTECTION

1. Nutritional Claims

From the contacts we had with the Ministry of Health, the representatives of the food industry sector and of the retail sector, we understand that there have not been major cases in which a nutritional claim or a health claim has been at the centre of a controversy over barriers to trade.

The only case which could be quoted is one relating to an energy drink (Red Bull), in 1996, and was cited by an official we spoke to in the Ministry of Health.

This energy drink had been prohibited in Italy because its caffeine content was higher than the limits foreseen in a Presidential Decree of 1958 (No. 719). The European Commission initiated a procedure of infringement against Italy for creating a barrier to trade within the European market.

Facing the possibility of condemnation by the European Court of Justice, the Italian Health Superior Council conducted a study on the effects of the high contents of caffeine and taurine. On the basis of the findings of this study, the Ministry of Health adopted a Ministerial Circular (No. 5, 3 April 1998), which allowed the marketing of "Beverages coming from another EC Member which are characterised by high level of caffeine and taurine".

This document also provides for some indications on what has to appear on the label (see annex 7).

Relying upon the findings of the Italian Health Superior Council, the Ministerial Circular states that beverages containing 320mg per litre of caffeine and 4g/litre of taurine do not pose particular danger to public health.

However, with specific reference to the information to be put on the label of these beverages, the circular states the following:

"*Considering the content of caffeine, it is particularly necessary to provide a correct and adequate information for the consumer through the wording and the warnings on the label. It is opportune to indicate those individuals who are exposed to risk (children, pregnant women and particularly sensitive individuals), and to suggest a moderate consumption [of these beverages] in case of contemporary consumption of caffeine from other sources.*

Allegations on the beneficial effects of these beverages, which, at the current status of knowledge, cannot be adequately documented, cannot be put on the label.

Among the warnings, it is opportune to insert also the advise of avoiding the contemporary exposure to alcohol and tobacco."

The Italian ban on the commercialisation of this kind of beverages was based on considerations aimed at granting a higher level of consumer protection.

2. Health Claims

Although we could not find any cases in which a health claim had been at the basis of a controversy on trade barriers, the possibility of having one was mentioned by the food industry sector.

According to the food industry, disputes over barriers to trade could arise if a code of self regulation exists in one EU Member State which allows the use of certain health

claims. In this case, the importation of this kind of products into the Italian territory could pose some problems.

As health claims are currently not allowed, there is no problem of consumer protection in this field.

According to the food industry, should health claims be allowed, this would result in a higher level of protection not only for consumers, but also for producers. As a matter of fact, each food producer would check that what a competitor says on a package is in conformity with the rules on health claims, and would ask for the intervention of the judiciary power in case of a breach of the law.

3. Ethical Claims

With regard to the proposed Act on the "Certification of social conformity of those products realised without making use of child labour", Article 4 of the law explicitly makes reference to the risk of distorting competition among different firms.

Literary, the provision of the law reads:

"*The President of the Council [the Prime Minister] will watch at that the Register will not improperly managed to distort the freedom of competition between the enterprises*".

This is a clear reference to the risk of creating trade barriers based on the new social label that will be introduced after the entry into force of this new law, should it be adopted.

According to the representative of the retail industry, the intention to put on packages this kind of ethical label will not benefit the consumer. As a matter of fact, there are already too many symbols on the package, and this new one would only add to the customer confusion.

III. VOLUNTARY INSTRUMENTS USED

A. VOLUNTARY INSTRUMENTS IN PLACE

A self-regulation advertising system was set up in Italy in 1963, but the first advertising Self-Regulation Code was only adopted on 21 May 1966, when the Advertising Self-Regulation Institute (IAP, which stands for Instituto dell'Autodisciplina Pubblicitaria) was also created. The advertising industry (operators and creators) adhere to this Code.

Since 1966, the Self-Regulation Code has been updated and amended several times. The last amendment to the Code was adopted in May 1999, and now the 29th version of the Code is in force (see annex 10).

The aim of the rules in the Code is to set-up guidelines about what can be considered as correct and lawful communication.

Although not an official document, this Code has received wide appreciation, and was included in the collection of "uses in the field of advertising" by the Chambers of Commerce in Milan, Turin, and Bari.

The role of the IAP partially overlaps the role that was given in 1992 to the Antitrust Authority in the field of misleading advertising.

Moreover, the IAP plays an important role in the advertising of pharmaceutical products. According to an Italian Decree of 30 December 1992, No. 541, companies that produce advertisements for pharmaceutical products to be sold over the counter, can submit their advertisements for prior approval to a "self-regulatory institute". The Minister responsible for Health has identified this institute as the IAP.

On 10 December 1996, a working group within the Ministry of Health elaborated and adopted an internal document which has not been officially published and which provides rules for diet integrators (see annex 12).

This document, (please find a copy annexed) specifies the values of each vitamin and mineral, which can be contained in food, and provides specific definitions of each kind of integrators: energy and protein, lipid, biological, fibre integrators.

It is interesting to point out that, when referring to integrators "*with a health component*"; the Ministerial guidelines bar the possibility of those integrators that have among their ingredients herbs which are known for their pharmaceutical properties.

What is equally interesting to note is that these guidelines also have a specific part dedicated to labelling. In this section, the Ministry also provides some guidelines on nutritional labelling. According to the Ministry:

"*The reference to a specific physiologic activity of the various nutritional components which is clearly documented, especially in case this reference is useful to favour a more aware choice among the products, is admitted.*

Reference to a specific function is admitted when it is clearly documented (i.e. calcium for the bones, fluorine for teeth enamel and anti-caries action).

Reference to particular metabolic roles are admitted when they are clearly specified and documented.

For the essential nutrients, reference to their use has to be done in case of reduced contribution with the common food portion".

The document of the Ministry also states:

"*When the claims*[23] *"with no sugar/s" or "with no added sugar" are used, there is the obligation of having a nutritional labelling listing all the information, with a specific reference to the "sugars".*

So far the Ministry has accepted only a limited number of nutritional claims that the producer can use when referring to the effects of a specific component of the food integrator:

Chrome: "*it also plays a role in the metabolism of the sugars and of the lipids"***.**

Lipotrops factors: "*they positively acts on the metabolism of the lipids*".

Fosfatidilserina: "*it plays a role as modulator of the biochemical-metabolic process at brain level*".

Antioxidant and bioflavonoidi vitamins: "*among the other effects, also the function of the micro-circulation*".

These ones listed above are the only claims, which can be put on the label by producers when referring to these substances. There is currently a working group, which meets in the Ministry of Health to analyse labels and the claims on them. It is composed of nutritional and pharmacological experts. So far, this working group has accepted very few claims.

B. DEFINITIONS USED IN THE VOLUNTARY INSTRUMENTS

In the Self-Regulation Code no definition is provided for nutritional claims, health claims or ethical claims.

C. EXISTING PROHIBITIONS, RESTRICTIONS AND EXEMPTIONS

The IAP Self-Regulation Code contains several prohibitions and restrictions regarding the message, which can be used to advertise certain particular products. Precise guidelines are given for the advertising of alcoholic products, but also for cosmetic products, food integrators and dietetic products, medical products and healing treatments.

1. Nutritional claims

On food integrators and dietetic products, Art. 23 bis of the Self-regulating Code states that:

"*Advertising of food integrators and dietetic products shall not claim properties which are not in conformity with the particular characteristics of the products, or properties which are not really owned by the products.*

[23] Claim in English in the Italian text.

Moreover, this kind of advertising does not have to be made in a way such as to induce consumers to make nutritional mistakes, and it has to avoid making reference to medical recommendations or statements".

2. Health claims

The Code makes reference to the prohibition of using health claims in several of its provisions.

With regard to cosmetic products, the Self-Regulating code makes implicit reference to health claims in Article 23, by saying that:

"*although cosmetic advertising can present these products [cosmetics] as having subsidiary features for the prevention of particular pathologic situations, provided that they have specific ingredients and formula to that aim, it does not have to induce the consumer to make confusion between cosmetic products and products for personal car on one hand and medical products and healing treatments on the other hand*".

In Article 24, referring to "Physical or aesthetic treatments", the Code states that advertising

"*shall not induce to believe that these treatments have therapeutic effects […] or have the capacities to produce radical results, and shall avoid reference to medical recommendations or statements*".

The Code also contains a specific article on the advertising of medical products. There is also a specific regulation, which sets up the rules for the Section of the monitoring body instituted by the Code, which deals specifically with pharmaceutical products. (See annex 11).

D. VOLUNTARY INSTRUMENTS ACCEPTED/RECOGNISED BY THE AUTHORITIES

As we have mentioned, the Code published by the IAP has been retained as a benchmark that is used by several Chambers of Commerce.

IV. VERIFICATION SYSTEMS

A. CRITERIA FOR SUBSTANTIATING CLAIMS

1. Nutritional Claims

Apart from the criteria for nutritional labelling, as set out in the nutritional labelling Decree (No. 77 of 16 February 1993, see annex 1), the relevant sections of the Decree 111 of 1992 on foodstuff for particular nutritional uses (see annex 3) applies. For such foodstuffs the manufacturer or importer has to notify the Ministry of Health of its placing on the market by transmitting a model of the label. The Ministry may require the manufacturer or the importer to also provide scientific data to justify the particular nutritional use of the product (article 7).

The Ministry of Health issued in 1996 Circular No. 8 (see annex 13), which states that foodstuffs with added vitamins and minerals, as well as diet integrators also fall under the notification procedure of foodstuffs for particular nutritional uses. The Ministry of Health indicated that it felt that as long as there existed no EU legislation for these products, a certain control was needed.

Furthermore, under the Italian Decree on foodstuffs for particular nutritional uses, the product categories listed in Annex I (which are the same as the one listed in EEC Directive 89/398) require a marketing authorisation from the Ministry of Health, until specific Decrees have been adopted for these products (i.e. once EU Directives have been adopted for these products, which are then implemented by Decrees in Italy). For these products, the manufacturer has to send to the Ministry a sample of their product within three months of beginning production.

2. Health Claims

Health claims are not allowed in Italy.

3. Ethical Claims

According to the draft proposal for a law on the social certification on the use of child labour, companies which want to sign up to the Register which will give them right to make use of the apposite social label for their products, simply have to sign. No special requirement or control is needed.

It is interesting to note that Article 4 of the draft law on the social conformity label states that the office of the Prime Minister will pay attention to the managing of the Register established by the law. This will not alter the free competition among manufacturers.

B. LEGAL/ADMINISTRATIVE SYSTEMS FOR VERIFYING CLAIMS

1. Pre-Clearance Rules/ Guidelines

a. Nutritional claims

As mentioned above under the Decree 111/92 on foodstuff for particular nutritional uses (see annex 3), for the products not listed in Annex 1 a notification procedure is mandatory.

In the case of the marketing of a new product, which is thus not on the list of Annex 1, the manufacturer or the importer has to inform the Ministry of Health, by transmitting a model of the label used for such a product. In cases where these products have already been sold in another EU Member State, the manufacturer or the importer will also have to notify to the Ministry of Health and the recipient authorities of the first notification.

Whereas the products, which have been notified to the authorities, do not fall in the category of foodstuff for particular nutritional uses as described in Article 1,

paragraph 2 of the Decree, the Minister for Health can ask the companies concerned to withdraw these products from the market. In a case where the company does not withdraw the product, the Minister of Health can sequestrate it.

Moreover, as foreseen in the Directive, the Ministry of Health can also sequestrate those products, which present a danger to human health. Both in this case and in the previous one, the Ministry has to inform the European Commission and the other EU Member States of the measures adopted and of their reasons.

If the Ministry of Health believes that a product falls within the category of those listed in Annex 1, it can prohibit its sale, and submit it to the authorisation procedure provided with by Article 9, which is foreseen for Annex 1 products.

For all those products, which are listed in Annex 1 of the decree, production and importation are submitted to an authorisation of the Ministry of Health. However, as mentioned above, this procedure applies only until the Ministry of Health does not adopt *ad hoc* ministerial decrees for every and each of the categories of products in Annex 1. So far, decrees have been adopted for infant formulae, baby foods, follow-up milk and foods, as well as foods intended for weight control.

As the company applies for an authorisation, the company has the legal obligation to keep at the Ministry of Health's disposal the samples of the product for which it demands the authorisation. In any case, within three months from the beginning of the production of the product, the company itself has to send a sample of the product to the national Health Superior Institute, which informs the Ministry of Health of the results of the analytical controls.

b. Health claims

Health claims are not allowed in Italy.

The industry sector does not believe that a pre-clearance control for example by the Ministry of Health would serve the scope, as it would be far too heavy. It considers that some general guidelines have to be set-out at EU level, so that they are uniformly applied in all the EU Members.

Moreover, having a preventive control by the Ministry of Health, and maybe a clearance of the label and of the claim on the label, would not – in the interviewee's view – give the producer the certainty of not facing a complaint by the consumer in front of the Antitrust Authority or in front of a normal judge. As a matter of fact, the judicial power in Italy is completely separated from the Public Administration. This means, for example, that the police could always intervene on a consumer's request, and that a Ministerial Circular on a specific product would not hamper the judge to act.

Moreover, having pre-clearance from the central Ministry would not give any certainty about a real uniform interpretation by all the different ASL (Local Health Authority), which are responsible in every district, and which, *de facto*, have often given very different interpretation of the documents and guidelines provided by the central authority.

c. Ethical claims

Please refer to the section II.E on ethical claims, where the procedure foreseen by the law currently under discussion within the Italian Parliament is explained.

2. Post-Clearance Rules/ Guidelines

a. Nutritional Claims/ Health Claims

The present control system foresees that the so-called NAS, Nuclei Anti Sofisticazione, which is a branch of one of the two Italian police forces (carabinieri), have the specific task of ensuring that no crimes are committed in the field of food safety and hygiene. Once the NAS is called into action, whereas they find something, which could constitute a violation of the law on foodstuff, the judge can start a procedure against the producer.

According to the representatives of the food industry, the real control on the compliance with the interdiction of health claims is exercised by the industry itself.

As a matter of fact, when there is a manufacturer who makes use of a health claim on the packaging of one of its products, the first to intervene are its competitors, who get in touch with this manufacturer to convince it to stop the use of the claim. This approach is usually successful, as the threat to bring the issue in front of a court is a useful tool of persuasion.

b. Ethical claims

The subscription to this Register has to be renewed every three years. In case the firm does not renew its decision to be included in the Register, the specific Monitoring Committee, which is instituted by the law itself, will take care of deleting the product or the firm from the Register.

The Monitoring Committee will present a yearly report on the status of implementation of the law. This report will have to be presented to the Parliament and to the Government by 31 May of each year.

The Monitoring Committee will have the task of checking on a random basis whether the companies included in the Register fulfil the obligation not to use child labour. In case the Monitoring Committee finds out that there are violations, it can decide to exclude the products concerned or the company from the Register. When it deems it necessary, the Monitoring Committee can also publish the decision to exclude a product or a company from the Register.

c. Out-of-Court Procedures

The Self Regulation Code on advertising of the Institute for the Advertising Self-regulation foresees a precise procedure for verifying claims.

There are two separate organs, the Jury (*Giuri)* and the Committee of Control (*Comitato di Controllo)*. The Jury is made of up of between 9 and 15 members and is responsible to analyse cases of possible violations of the Self Regulating Code which are transmitted by the Committee of Control, made up of between 10 and 15 members.

According to Article 36 of the Code,

"*Whoever believes to suffer from prejudices deriving from advertising activities in breach of the Code of Self-regulation may ask for the intervention of the Jury against those who, having accepted the norms of the Code […] have committed those activities which are deemed prejudicial"*.

When the Jury decides that a certain piece of advertising is in violation of the Code, then it can ask the economic operator in question to suspend its use. In case the economic operator does not comply with the decisions of the Jury, the Jury can decide to make public this refusal in the newspapers, in magazines or on television.

C. LEGAL PERSONS ENTITLED TO TAKE LEGAL ACTION

Any legal person can demand the intervention of the NAS.

Moreover, on the basis of the Italian law on misleading advertising, the following persons are entitled to bring a case in front of the Antitrust Authority:

- the competitors;
- the single consumer, the consumer associations or organisations;
- the Ministry of Industry;
- the Ministry of Trade; and
- any other public administration, also on the demand of the public.

D. BURDEN OF PROOF

The burden to prove that a certain product has not the characteristics, which have been put on the claim, is on the plaintiff's shoulders. However, it is normal that the company that is investigated will tend to provide all the information to demonstrate that what was said on the package was real.

However, the norms on misleading advertising have different provisions. As a matter of fact, the Antitrust Authority can ask the advertising operator (the person who has commissioned the advertising or its creator)

"to provide the proves on the material accuracy of the data contained in the advertising if, considering the rights or the legitimate interests of the advertising operator and of whatever other party in the procedure, this can be justified, taking the specific situation into account. If such a proof is not given or is considered not sufficient, the data shall be considered inaccurate"(article 4).

E. APPLICABLE PENALTIES

1. Nutritional claims and health claims

According to the Decree 77 of 1993 implementing Directive 90/496 on the nutritional labelling of foodstuff (see annex 1),

"*whoever manufactures, keeps for sale or sales products which are not in conformity with the rules of the present Decree is punished with the administrative sanction which consists in paying an amount of money included between 1.250.000 liras and 7.500.000 liras*" (646 and 3.874 Euro).

With regard to foodstuff for particular nutritional uses, the Decree 111 of 1992 implementing the Directive 398/89 (see annex 3) foresees different sanctions, which depend on what articles of the Decree itself is violated.

In case of a violation of Articles 1, 2, 3, 4, 5 and 6 (which contain the norms on the labelling of the foodstuff), the punishment consists of paying between 2 million and 12 million liras (1.033 and 6.198 Euro).

In case of a violation of Article 7 (which contains the rules on the sale of the foodstuff), the amount of money to pay is between 1 and 6 million liras (516 and 3.099 Euro).

In case someone imports foodstuff, which should be submitted to the authorisation procedure foreseen in Article 8, he will be sanctioned with a fine of between 10 and 60 million liras (5.160 and 30.990 Euro).

As health claims are not allowed in Italy, in case a manufacturer makes use of them, this will constitute a violation either of Decree 77/93 or of the Decree 111/92, depending on the kind of product.

For cases that have been brought to the Antitrust Authority, these are judged on the basis of the misleading advertising law, which foresees that the Antitrust Authority can order a provisional ban of the advertising in case of urgency and/or it can order the complete ban of the advertising. The Antitrust Authority is a collegial body, which takes its decisions by majority voting (it is composed of 5 members). If an advertising operator does not follow the order of the Antitrust Authority, he can be fined with up to 3 months imprisonment in conjunction with a fine of up to 5 million lira. Decisions of the Antitrust Authority can be appealed to an administrative court.

2. Ethical Claims

Penalties applying to ethical claims fall under the misleading advertising law.

V. CASE LAW

A. PERTINENT CASE LAW

1. Nutritional Claims

It has proved impossible to find a case debated in an Italian Court which had a controversy on a nutritional or a health claim as its basis.

According to the Ministry of Health, this is due to the fact that the food producer, before putting a product on the market, asks the Ministry whether it thinks that the label and the claims conform to the national legislation.

This sort of preventive control, which is not foreseen by the law, works well in preventing these cases from reaching court.

Moreover, according to the representative of the food industry, when there are claims that possibly violate the law, by saying something about a product which according to the current laws cannot be said, the competitors themselves intervene to block this kind of claim by acting directly against the producer.

This kind of approach is also used for TV advertising: when there is a producer who makes a TV advertisement which refers to, for example, the beneficial effects of a given product on human health, the same competitors act to stop it. The practice of stopping such advertising seems to warn the company that its competitor may ask a judge to look into this issue, or by simply asking a consumer association to intervene.

There have been two cases: one case against an aspartame producer, and one case against a specific kind of milk whose TV advertising was making reference to some beneficial effects for the human heart. In both cases, after the intervention of the competitors, the TV advertising was suspended "voluntarily" by the producer, without the issue going to court.

However, the Antitrust Authority has analysed several cases in which nutritional claims have been called into question.

The Italian Antitrust Authority, *Autorita' Garante per la Concorrenza ed il Mercato*, is an independent administrative authority, not a judicial one. As mentioned above, the Antitrust Authority is a collegial body, which takes its decision by majority voting (it is composed of 5 members).

In 1992, the Antitrust Authority was also given the competence to rule on the respect of the norms on misleading advertising.

In one of the cases decided on the basis of the misleading advertising rules, the *Pharmalife Italia* case of 1997 (see annex 21), the Antitrust Authority analysed the claim and the advertising of food integrators, which are regulated in Italy by Decree 111/92.

The case focused on several integrators produced by the company Pharmalife. The company had regularly transmitted the labels to the Ministry of Health, as foreseen in the Decree 111/92, and the Ministry of Health had authorised most of the claims on the labels, asking for some of the claims to be changed as they were making reference to therapeutic properties of the products. The producer complied with the requests of the Ministry of Health.

However, according to the Antitrust authority, the claims used by Pharmalife to advertise its products on leaflets and in brochures constituted a case of misleading advertising. As a matter of fact, the producer was describing its products in the leaflets as sport products or as integrators having particular features, although these claims were not on the actual label of the products.

The Antitrust Authority decided that the claim on the advertising materials could have made the consumer think that the products had characteristics that did not actually exist, and hence the advertising was declared misleading, even if the nutritional information on the label of the packages was correct.

Another case on a nutritional claim decided by the Antitrust authority on the basis of the misleading advertising is the *Cuore Oil* case, of 1997 (see annex 22).

According to a consumer, the claims used in the advertising of this particular oil were misleading. The plaintiff focused on the fact that many of the claims used were unfounded, as the actual content of the oil could not have the effect claimed.

This oil had been advertised with claims such as:
- *with Cuore Oil lightness wins;*
- *with Cuore Oil unsaturated acids win; and*
- *health and youth of our cells win*.

According to the consumer who complained, the virtues claimed by the Cuore oil were misleading, as the Cuore Oil had exactly the same characteristics as all the other oils.

The Antitrust Authority concluded that the advertising of this oil was fully in compliance with the existing legislation, and that all the claims used by the company producing the Cuore oil were well founded.

In particular, the Antitrust Authority recognised that the Cuore oil was a specific dietetic product, which conformed to the requirements of the Decree 111/92. Moreover, the producer was successful in providing scientific data to demonstrate all the properties described in the claims.

2. Health Claims

There are no cases on health claims that have been judged by Italian courts. Nevertheless, one was decided by the Italian Antitrust Authority. Once again, it was focused on the advertising of Cuore Oil.

In the case known as Cuore Oil II of 1998 (see annex 23), the Antitrust Authority analysed an advertisement that appeared in an Italian newspaper, in which various claims described the Cuore Oil as a foodstuff which had "*a wide range of positive effects on health*".

This claim was supported by means of a series of other claims which tried to explain to what extent the nutrients contained in this particular oil had positive effects on human health, in particular with reference to heart-vascular diseases, diabetes, arteriosclerosis and tumours.

The Antitrust Authority, after a long analysis of the scientific elements, came to the conclusion that none of the nutrients present in Cuore Oil could have a sure beneficial effect on the human diseases indicated in the claims.

Moreover, and more interestingly, the Antitrust Authority made explicit reference to Article 6 of the Decree 111/92, which explicitly says that the presentation and the advertising of foodstuff for particular nutritional uses shall not either imply characteristics aimed to prevent, cure or heal diseases, or mention such characteristics.

On the basis of this provision and of the lack of scientific data which supported the health claims provided by the advertising of Cuore Oil, the Antitrust Authority declared the advertising misleading, and banned its further diffusion.

3. Ethical Claims

Considering that the law on "Certification of social conformity of those products realised without making use of child labour" still has to be finally approved by the Italian Parliament, it is impossible to present case law decided on that basis.

No cases on ethical claims are known.

VI. MEANS OF COMMUNICATION

There is no difference between the means of communication.

However, in cases where the Antitrust Authority is called to decide on the basis of the legislation on misleading advertising, it has to ask for the advise of the Authority responsible for monitoring broadcasting and publishing (Garante per la Radiodiffusione e l'Editoria) when the advertising was either broadcasted on TV or published on the press.

VII. STATISTICS ON CLAIMS

Real statistics on nutritional and health claims were not available. However, the Antitrust Authority responsible for misleading advertising has published some data, which are useful.

In the period 1992-1997, the cases analysed by the Antitrust Authority on misleading advertising had been raised by the following plaintiffs:

- 41% consumers;
- 27% various associations;
- 20% competitors;
- 11% public administration; and
- 1% others.

In the period 1992-1997, the Antitrust Authority analysed a growing number of cases related to misleading advertising. The number of cases which have been recognised as misleading increased as well: in 1992 only 35% of the cases analysed turned to be misleading, while in 1996 they were 73%, with more than 350 cases examined.

Regarding the number of misleading messages found per communication tool used, the statistics for the period 1992-1997are as follows:

- 63% press;
- 68% leaflet and brochure and publications;
- 67% TV;
- 79% post;
- 49% package;
- 61% posters;
- 58% radio;
- 100% telephone (only one case).

The areas which presented the highest number of misleading advertising per number of cases analysed in the period May 1992-April 1997 are:

- Instructions and publishing, with more than 150 cases analysed and around 67% of the cases found misleading;
- Trade, with more than 130 cases, and around 69% found misleading;
- Cosmetic and health care, with more than 100 cases, and around 70% found misleading;
- Tourism and travels, with 60 cases, and 38% found misleading
- Food, with 42 cases and only 14% found misleading.

VIII. ANNEXES

Legislation

1. Decree 16 Febbraio 1993, No. 77, implementing EEC Directive 496/90 on nutritional labelling of foodstuff.
2. Decree 27 Gennaio 1992, No. 109, implementing the EEC Directive No. 395/89 and No. 396/89 on labelling, presentation and advertising of foodstuff.
3. Decree 27 Gennaio 1992, No. 111, implementing the EEC Directive No. 398/89 with regard to foodstuff for particular uses.
4. Circular of the Ministry of Health No. 8 of 7 June 1999 on sport foodstuff.

5. Decree by the President of Republic No. 272 of 30 June 1998 amending norms on production and commercialisation of the beer.
6. Law No. 313 of 3 August 1998 on labelling of oilve oil 'extra vergine', olive oil 'vergine' and of olive oil.
7. Circular of the Ministry of Health No. 5 of 3 April 1998 on "Beverages coming from another EC Member which are characterised by high level of caffeine and taurine".
8. Decreto Legislativo 25 Gennaio 1992, No. 74, implementing the EC Directive 450/84 on misleading advertising.
9. Draft adopted by the Senate of the Italian Republic, but not yet by the House of Representatives, on the "Social Conformity Certification for products realised without the use of minors' work".
10. Self-regulating Advertising Code by the Institute for Self-regulating Advertising Institute.
11. Regulation by the Institute for Self-regulating Advertising on the Pharmaceutical section of the monitoring committee.
12. Internal guidelines of the Ministry of Health on food integrators (unpublished document)
13. Decree by the Ministry of Health No. 519, of 7 October 1998 implementing EU Directive 8/96 on foodstuff destined to ipo-caloric diets aimed at weight reduction.
14. Circular of the Ministry of Health No. 8 of 16 April 1996 on foodstuff integrated with vitamins and/or mineral and integrators.
15. Decree 30 November 1991, No. 425, implementing Articles 13, 15 and 16 of the EEC Directive 552/89 on television advertising of tobacco products and alcoholic beverages and on the protection of minors.
16. Act of 6 Agosto 1990, No. 223: discipline of the public and private television system (known as Mammi' Act).
17. Decree by the President of Republic 27 Marzo 1992, No. 255 – Regulation implementing the Law 223/90 on the discipline of the public and private television system.
18. Decreto Legislativo 28 Agosto 1995, No. 356 – Urgent provisions on the budgets of those enterprises active in the publishing and broadcasting sector, and on the prosecution of activities of television and radio broadcasters which have an authorization at local level.
19. Decreto del Presidente della Repubblica No. 627, 10 October 1996 – Regulation setting up the rules for the preliminary procedures of the Authority responsible for the competition with regard to misleading advertising.
20. Decree by the Ministry of Health No. 518, of 1 June 1998 implementing the EU Directive 4/96/CE on foodstuff for suckling babies.

Case Law

Autorita' Garante per la Concorrenza ed il Mercato (Antitrust Authority):

21. Case No. 4568 of 1997, Olio Cuore;
22. Case No. 5228 of 1997, Pharmalife Italia;
23. Case No. 6124 of 1998, Olio Cuore II.

IX. DATABASE OF CONTACTS

K. LUXEMBOURG

I. EXECUTIVE ANALYSIS

A. INTRODUCTION

The study on nutritional, health and ethical claims was generally well received by all interested parties in Luxembourg. Overall, interested parties were pleased that DG XXIV was taking an interest in these issues.

B. MEMBER STATE POLICY

1. Nutritional Claims

The definition of a nutritional claim is the same as defined in EU law.

2. Health Claims

With regard to health claims, these are banned under the national implementing legislation of Directive 79/112. Luxembourg legislation on the one hand implements Directive 79/112 word by word. But in addition, further provisions are made under Luxembourg legislation, which somewhat extends the prohibitions of Directive 79/112.

The use of certain enhanced function claims, as defined under the latest Codex draft recommendations for the use of health claims, seems to be rather limited under Luxembourg legislation. The reduction of the risk of disease claims, as defined under the same Codex draft, are clearly not permitted under Luxembourg legislation.

No legislative initiatives are foreseen with regard to nutritional, health or ethical claims, nor is there any ongoing discussion on these issues taking place in Luxembourg.

3. Ethical Claims

Ethical claims seem to be a non-issue in Luxembourg. Neither any specific labelling schemes have been developed in Luxembourg, nor are any political or regulatory initiatives planned.

C. VOLUNTARY CODES OF PRACTICE

No voluntary codes of practice exist in Luxembourg, moreover, no such codes are planned, with the exception of "Transfair Minka Luxembourg."

D. VERIFICATION SYSTEMS

With regard to the criteria for substantiating claims, the only ones applying are those set out in the law on nutritional labelling. As for dietary foods, the ones set out under the notification procedure of dietary foods apply.

There exists no pre-vetting in Luxembourg. A posteriori controls are undertaken by the Laboratoire National de Santé, the Inspection Sanitaire (Health Inspection Service) of the Ministry of Health, and by the police (control of markets).

The burden of proof lies with the complainant. Penalties can range from 1000 to 30000 Luxembourg Francs and/or 8 days to one year imprisonment.

E. MEANS OF COMMUNICATION

There are no differences between the means of communication.

F. CONSUMER PROTECTION

The consumer associations and the government feel that single-market rules and more specifically the obligation to allow the marketing of a product on the Luxembourg territory if it is allowed on the territory of another Member States creates difficulties. The Luxembourg administration does not have the resources to control every products entering its market and hence fear that the protection of consumers might not always be guaranteed. Hence, Luxembourg can only rely on the controls made in other European countries.

Similarly, judicial redress procedures are difficult to use in Luxembourg, since in most cases the producer of the product does not operate on the territory of Luxembourg and if its claims are accepted in another Member States, it is difficult to challenge them in Luxembourg.

G. BARRIERS TO TRADE

No barriers to trade have been reported. This is due on the one hand to the fact that there is only a very small Luxembourg food industry and, on the other hand, to Luxembourg's proximity to the markets of its neighbouring countries. In this way, it is basically forced to accept their products on its market.

H. CASE LAW

There exists no case law on nutritional, health or ethical claims in Luxembourg.

I. STAKEHOLDER ANALYSIS

Luxembourg, being the smallest EU market, is in general forced to allow the marketing of all products that are already on the market in other Member States. In particular, as Luxembourg does not have the necessary resources to control every product entering its market, the authorities consider the development of a control at a European level a potential solution to problems of consumer protection.

In conclusion, the positions of the main stakeholders are:

1. Government Authorities

- The authorities are in favour of a control of claims at the European level.

2. Consumers

- Equally, consumer associations are in favour of a control of claims at the European level.

- On ethical claims, the Luxembourg fair trade association considers that the certification of fair traded products needs, in the medium-term, to be regulated at international level.

3. Industry

- There is no position.

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II. MEMBER STATE POLICY

A. DEFINITIONS OF CLAIMS

1. Nutritional Claims

The Règlement Grand-Ducal of 22 June 1992 on Nutrition Labelling (see Annex 1) defines a nutritional claim as "any representation and advertising message which states, suggests or implies that a foodstuff has particular nutrition properties due to the energy (calorific value) it

- provides,
- provides at a reduced or increased rate, or
- does not provide,

and/or due to the nutrients it

- contains,
- contains in reduced or increased proportions, or
  does not contain."

Luxembourg legislation, therefore, implements word by word the EU Directive 90/496.

2. Health Claims

There is no definition of health claims as such in Luxembourg legislation. However, the Règlement Grand Ducal of 16 April 1992 on the labelling and presentation of foodstuffs (see Annex 2) provides for a negative definition. It states in article 15 (2) that it is forbidden to attribute to a foodstuffs properties "of preventing, treating or curing a human disease". In addition article 16 states that:

"…it is forbidden to use in the labeling of foodstuffs:

1. names of diseases and any allusion to diseases or to people suffering from a disease;
2. names or representation, even in abstract form, of organs or circulatory and nervous systems that may imply that the foodstuff has such effects;
3. representations or people, clothes, or machines relating to the medical, para-medical or pharmaceutical activities;
4. references to recommendations, attestations, declarations or medical advises, except if it is to mention that the foodstuff does not suit certain diets;
5. reference to the Ministry of health;
6. references to weight loss diets;
7. any indication referring to health in general such as "supporting" [réconfortant], "fortifying", "energizing", "for your health", 'vitalizing' of foodstuffs or of products consumed for pleasure that contain alcohol;
8. claims that may - exploit or provoke anxiety;
   - discredit similar foodstuffs."

Furthermore, article 17 of the same law, forbids:

"claims referring to objective and measurable elements, which cannot be justified", as well as "references to an effect of the foodstuff on health or the metabolism, if the proof of that claim is not provided, without prejudice of the provisions of article 16 above"

In addition, labelling and methods used in labelling that are misleading are forbidden. In particular, those attributing to a foodstuff effects or properties that it does not have, and by suggesting that a foodstuff has particular characteristics, when all similar foodstuffs have the same characteristics (article 15 (1.2.) and (1.3.)).

Luxembourg legislation is thus implementing word by word article 2 of the EU Labeling Directive 79/112. However, a number of further provisions are made, which extend the prohibitions of Directive 79/112.

Under Luxembourg legislation, the use of certain enhanced function claims, as defined under the latest Codex draft recommendations for the use of health claims, seems to be rather limited. Disease risk reduction claims as defined under the same Codex draft are clearly not permitted under Luxembourg legislation.

3. Ethical Claims

There is no definition of ethical claims in national legislation.

B. LEGISLATION IN PLACE

1. Nutritional Claims

Nutritional claims are regulated by the Règlement Grand-Ducal of 22 June 1992 on the nutritional labelling of food products (as last amended in 1998) (see Annex 1) and implements Directive 90/496.

The regulation provides that nutritional labeling is mandatory if the labeling of foodstuffs contains nutritional claims.

2. Health Claims

The Règlement Grand Ducal of 16 April 1992 on the labeling and presentation of foodstuff (see Annex 2) regulates the use of health claims and implements Directive 79/112.

Foodstuffs for particular nutritional uses are regulated by Règlement Grand Ducal of 8 April 1991 (as last amended in 1997) (see Annex 3) and implements Directive 89/398.

Misleading Advertising is regulated by the Law of 27 November 1986 on Certain Commercial Practices and Sanctioning Unlawful Competition (as last amended in 1992) (see Annex 4). It implements Directive 84/450.

3. Ethical Claims

There is no specific legislation on ethical claims.

C. EXISTING PROHIBITIONS, RESTRICTIONS AND EXEMPTIONS

1. Nutritional Claims

Mineral waters and foodstuff for particular nutritional uses are not within the scope of the national legislation on nutritional claims.

2. Health Claims

In principle, all health claims are forbidden.

3. Ethical Claims

There is no specific legislation on ethical claims. Therefore, the general Law of 27 November 1986 on Certain Commercial Practices and Sanctioning Unlawful Competition applies to such claims.

Under article 17 of this law dealing with "false indications", it is considered unlawful competition inter alia when an economic operator makes wrong indications which mislead the consumer, as well as inexact indications on the nature of the product its conditions of productions and its quality (notably para. a) and i) of article 17).

D. POLICY DEVELOPMENTS AND STAKEHOLDERS' POSITIONS

There is no ongoing discussion on the issue of nutritional, health and ethical claims in Luxembourg, nor are any legislative developments foreseen.

The consumer associations and the government feel that single-market rules and more specifically the obligation to allow the marketing of a product on the Luxembourg territory if it is allowed on the territory of another Member States creates difficulties. The Luxembourg administration does not have the resources to control every product entering its market and hence fear that the protection of consumers might not always be guaranteed. Hence, Luxembourg can only rely on the controls made in other European countries. The development of a control at a European level is seen as a potential solution to this problem (see also Annex 5).

The Luxembourg fair trade NGO (TransFair Minka) indicated that it was under the impression that large companies were sometimes using wording that implied that they were fair trading, without actually doing so.

III. VOLUNTARY INSTRUMENTS AND OTHER PRACTICES

1. Nutritional and Health Claims

There are no voluntary agreements or other practices with regard to nutritional and health claims.

2. Ethical Claims

The Luxembourg fair trade organisation, TransFair Minka, acts as an independent organisation selling licences for the use of its TransFair-Seal.

The seal guarantees that certain social standards are met in third countries (such as minimum salary paid, no child labour, guaranteed workers employment rights according to national and international law). Furthermore, the seal guarantees that certain environmental standards are being respected. TransFair Luxembourg is in principle using the same licensing agreements as TransFair Germany (see German report).

IV. VERIFICATION SYSTEMS

A. CRITERIA FOR SUBSTANTIATING CLAIMS

Article 7 of the Règlement Grand Ducal of 8 April 1991 on foodstuffs for a particular nutritional use provides that the producer or the importer of the product has to inform the Ministry of Health before the product is put on the market. The producer or the importer must forward an example of the labeling to the Ministry. The ministry can request the producer to provide the scientific evidence to substantiate its claims.

Furthermore, article 17 of the Règlement Grand Ducal of 16 April 1992 regulating food labelling, provides that references to the effect of a foodstuff on health or the metabolism may not be made, if the proof for that claim cannot be submitted. No further indications are made in this law, as to which kind of proofs need to be submitted.

B. LEGAL/ADMINISTRATIVE SYSTEMS FOR VERIFYING CLAIMS

A posteriori, controls are undertaken by the Laboratoire National de Santé, the Inspection Sanitaire (Health Inspection Service) of the Ministry of Health, and by the police (control of markets).

The control of advertising is undertaken by the pharmaceutical division of the Ministry of health.

C. LEGAL PERSONS ENTITLED TO TAKE LEGAL ACTION

The administration, consumer organizations and individuals are entitled to take legal action (see notably article 21 of the Law on Certain Commercial Practices and Sanctioning Unlawful Competition).

D. BURDEN OF PROOF

In terms of advertising, the burden of proof belongs to the producer marketing a product with the use of a claim.

However, if a product is already on the market, the complainant bears the burden of proof.

E. APPLICABLE PENALTIES

In practice, the producer is requested to modify its advertising or its labelling. In theory, infringements of the food legislation previously mentioned, are regulated by article 9 of the law of 25 September 1953 on the Reorganisation of Food Control (see Annex 6). The penalties established under article 9 range from 1 000 to 30 000 Luxembourg Francs and/or 8 days to one year imprisonment applies.

To violations of article 17 of the Law on Certain Commercial Practices and Sanctioning Unlawful Competition, which forbids operators to make wrong indications which mislead the consumer (see II.C)3.), the following penalties are applicable: firstly, an order by the Court to stop any acts contrary to this law; secondly, if the defendant does not conform to this order, a fine between 10,000 and 2 million Luxembourg Francs can be imposed. If within a period of five years an economic operator is for the second time ordered by the Court to stop any acts of unlawful competition, automatically a fine between 10,000 and 2 million Luxembourg Francs is imposed (article 21 and 22).

Judicial redress procedures are difficult to use in Luxembourg, since in most cases the producer of the product does not operate on the territory of Luxembourg and if its claims are accepted in another Member States, it is difficult to challenge them in Luxembourg.

The Luxembourg fair trade association considers that the certification of fair traded products needed in the medium-term to be regulated at international level.

V. CASE LAW

There exists no case law on nutritional, health or ethical claims in Luxembourg.

VII. MEANS OF COMMUNICATION

There are no differences between means of communication. The Règlement Grand-Ducal of 16 April 1992 on food labelling states in article 19 that it applies to the presentation, packaging, packaging material used and advertising of foodstuffs.

Furthermore, the Law of 27 November 1986 on Certain Commercial Practices and Sanctioning Unlawful Competition does not make any difference between means of communication.

VII. STATISTICS ON CLAIMS

We did not come across any statistics.

VIII. ANNEXES

1. Règlement Grand-Ducal du 22 juin 1992 relatif à l'étiquetage nutritionnel des denrées alimentaires
2. Règlement Grand-Ducal du 16 avril 1992 concernant l'étiquetage et la présentation des denrées alimentaires ainsi que la publicité faite à leur égard (version du 7 juillet 1998)
3. Réglement Grand-Ducal du 8 avril 1991 relatif aux denrées alimentaires destinées à une alimentation particulière (version du 4 novembre 1997)
4. Loi du 27 novembre 1986 réglementant certaines pratiques commerciales et sanctionnant la concurrence déloyale (version du 29 mai 1992)
5. Note du Laboratoire National de Santé
6. Loi du 25 septembre 1953, ayant pour objet la réorganisation du contrôle des denrées alimentaires, boissons et produits usuels.

IX. DATABASE OF CONTACTS

L. THE NETHERLANDS

I. EXECUTIVE ANALYSIS

A. INTRODUCTION

This study on nutritional, health and ethical claims has been conducted with the positive contribution of all parties concerned in The Netherlands. Whereas some parties concerned initially thought the idea of the study was born out of the dioxin crisis(!) everyone felt it was a very good initiative to map out the regulatory practice regarding claims and to highlight the areas in which DG XXIV eventually could intervene.

B. MEMBER STATE POLICY

1. Nutritional claims

The definition of a nutritional claim is the same as the one used in Directive 90/496/EEC. Claims related to nutrition but which do not concern the nutritional value, do not fall under this definition. On these, the rules with respect to the prohibition on the use of misleading claims and the use of medical claims are applied.

Policy thinking by the public authorities is that current legislation on nutritional claims is satisfactory and that restriction or extension of possibilities should take place on the basis of nutritional goals that are being pursued. Dutch regulatory practice regarding nutritional claims goes further than EU law and is considered satisfactory by the parties concerned. Apart from some fine-tuning regarding optional rules, there seems to be no need for adaptation. The only policy developments taking place in this field concern different types of fats.

2. Health claims

Dutch law does not contain any definition of health claims. However, relevant parts of Directive 79/112/EEC dealing with health claims have been implemented in The Netherlands via the *Commodities Act* ('Warenwet'). The Dutch policy and regulatory practice regarding health claims allows this type of claim for foodstuffs providing that they are true and not misleading. It is, however, forbidden to allude to medical claims.

In general, all parties concerned feel that the current policy regarding health claims is satisfactory. The public authorities play a supporting, but modest role, leaving room for self-regulation. There seems to be no immediate need in The Netherlands for new legislation regarding health claims at national level and most of the parties concerned do see the need for future legislative developments to be arranged at EU level.

Nevertheless, the Dutch foodstuffs industry feels that a clearer definition could cover borderline cases in the subtle field between *positive health claims* and *medical claims*. The industry considers that, under the conditions of the voluntary instruments in place, the Dutch Commodities Act should not prohibit health claims aimed at

preventing human diseases. Industry feels that this type of so-called *effect claims* could be captured under a code of practice.

It is worth noting here that over the past years a debate has been taking place in The Netherlands regarding functional foods, novel foods, food supplements and the verification problem of claims in this field.

3. Ethical claims

There is no legal definition of ethical claims and no directly relevant legislation in The Netherlands. Neither is there any specific policy. Nevertheless, the relevant articles from the Dutch Civil Code and the general guidelines under Part I of the Dutch Advertising Code that stipulate that advertisements must not be misleading or untrue are applicable to ethical claims. In particular, the rules in this section stipulating that advertising must not be gratuitously offensive or contrary to good taste and common decency refer to ethical claims.

In The Netherlands, the Ministry of Economic Affairs and the Ministry of Agriculture are responsible for social claims and animal welfare claims respectively. Currently, a project group under the Ministry of Economic Affairs is looking into consumer concerns. This might provide some information on public opinion towards ethical claims. For the Ministry of Agriculture, ethics, in general, play a role in its policy preparation regarding guaranteeing animal welfare and food safety.

C. VOLUNTARY CODES OF PRACTICE

1. Nutritional, Health and Ethical claims

While no specific voluntary instruments exist in The Netherlands for nutritional claims, there is one voluntary code relevant for all three types of claims and there exist some specific instruments for health respectively ethical claims.

a. Dutch Advertising Code

The most important voluntary code of practice regarding claims in The Netherlands, however, is the Dutch Advertising Code ('Nederlandse Reclame Code'), which contains rules that, in principle, apply to all three types of claims. It consists of two parts.

The first part of the Code contains general guidelines that stipulate, inter alia, that advertisements must not be misleading or untrue. This section also contains a number of rules based on subjective criteria. One of these stipulates that advertising must not be gratuitously offensive or contrary to good taste and common decency. The second part contains special guidelines and related rules for specific products and services. These were drafted in co-operation with self-regulatory bodies, such as the Foundation for the Responsible use of Alcohol ('Stichting Verantwoord Alcoholgebruik'), the Advertising Steering group Foundation ('Stichting Stuurgroep Reclame').

2. Health claims

There exist two voluntary codes regarding health claims in The Netherlands.

a. Code of Practice Health Benefits Health Claims

The Code of Practice Health Benefits Health Claims ('Gedragscode Gezondheidseffecten Gezondheidsclaims) aims to find evidence for health claims on foodstuffs to be scientifically founded and reported. This Code was initiated by the Dutch Nutrition Centre ('Voedingscentrum'), which is an independent non-profit organisation consisting of professionals in the food sector. This organisation facilitates the testing procedure, by bringing together a panel of independent academic specialists. The disadvantage of the Code of practice is that it concerns a heavy and expensive procedure, whereby the addressee has to go through prescribed stages.

The Code has been in force since April 1998 and, so far, three products are in the pipeline and, in the future, one can expect several margarine producers to make use of the testing procedure with a view to having their claims confirmed. Although a signatory of the Conduct Code, industry is still uneasy about the testing procedure and the functioning of the Code will be evaluated in two years time in order that it may be attuned to safety assessment methods.

b. KOAG/KAG Code for the advertisement of Health products

The highly regarded '*KOAG/KAG Code for the advertisement of Health products*' ('KOAG/KAG Code voor de aanprijzing van Gezondheidsproducten'), is mainly aimed at preventing the use of medical claims on health products. The Code was initiated by the Dutch Verification Council ('Keuringsraad'), a self-regulatory body for the public advertising of medicinal products (KOAG) and natural remedies and other health products (KAG), and has been in place for many years now. KOAG/KAG does not handle complaints.

3. Ethical claims

There exist two labelling schemes in The Netherlands regarding ethical claims, while a further two are being developed.

a. The Max Havelaar Trademark

The best known idealist scheme in The Netherlands is the 'Max Havelaar Trademark' ('Max Havelaar Keurmerk'). This is an instrument to help farmers in developing countries and thereby improve the country's economic situation. The trademark, with 32 licensees in the field of coffee, bananas, tea and cacao, was initiated because of a need among producers. The idea behind the trademark is to inform consumers.

b. Fair Trade Charter for Garments

Secondly, there is a 'Fair Trade Charter for Garments', which is a code of conduct for all retailers selling clothes in The Netherlands. This is part of the 'Clean Clothes

Campaign', an initiative to draw attention to the conditions under which garments are produced in developing countries.

c. Others

The Dutch organisation Fenecom is working on a trademark for the clothes-sector in The Netherlands under the name Fair Trade Charter for Clothes Foundation ('Stichting Eerlijke Handels Handvest voor Kleding'). The aim of the trademark is to support the International Labour Organisation (ILO) rules.

D. VERIFICATION SYSTEMS

The system for verifying claims in The Netherlands is twofold: on the one hand, there is the Health Protection Inspection/Commodities and Veterinary surgeons ("Inspectie Gezondheidsbescherming/Waren en Veterinairen"), a public authority appointed (market) supervisor, and on the other hand, there is the Advertising Standard Committee ("Reclame Code Commissie"), a private body and not a legal court in the strict sense of the word.

1. Health Protection Inspection

The Health Protection Inspection can initiate a post-clearance procedure (notifications of claims are only obligatory under the 'Directives for Special Foods') to prove that a particular claim is untrue. However, it usually works on the basis of complaints about non-compliance with the Commodities Act. The possibility for lodging a complaint is not limited to certain groups or persons however. The number of cases regarding claims dealt with by the Health Protection Inspection has been relatively small. According to the Inspection, this method has a preventive function.

As far as the procedure of the Health Protection Inspection is concerned, infringement of the rules on claims is considered an economic offence and is to be submitted to the Public Prosecutor who will notify the party concerned by means of a warrant. A first infringement will be penalised by a settlement consisting of a relatively little amount of money. In case of a second breach of the rules and when a claim is considered to endanger public health, the Public Prosecutor can eventually decide on taking a particular product off the market.

2. Advertising Code Committee

Real verification in The Netherlands is taking place by an Advertising Code Committee, set up by the Advertising Code Foundation ('Stichting Reclame Code'). The Advertising Standard Committee has the remit of assessing compliance of advertisements with the Dutch Advertising Code ('Nederlandse Reclame Code'). The committee does not work with a pre-clearance system - complaints are made to the committee. It is empowered to monitor advertisements on its own initiative. However, in practice it rarely does so, because monitoring is considered unacceptably arbitrary.

In the event of an appeal against the Committee's ruling, the matter is referred to the Appeals Board ('College van Beroep'), which issues a definite ruling. If an advertisement is found to infringe the Dutch Advertising Code, the Committee will

instruct the advertiser to stop using it in its current form. In the event of a repeat offence or a serious violation of the Code, the Committee-affiliated media will be instructed to stop publishing the advertisement concerned.

The Advertising Code Committee can ask anyone using a claim to prove that a particular claim is true. Until now, only a limited number of cases have been put before the Advertising Standard Committee. Most of the cases the Committee has been dealing with health claims and, in particular, borderline cases. This shows that there is a growing tendency in The Netherlands to use forms of medical claims. In its judgements, the Advertising Code Committee does not yet refer to the Code of practice Health benefits 1998.

The twofold verification system of claims in The Netherlands has not been functioning to the satisfaction of all parties concerned and could cause barriers to trade or lack of consumer protection as far as positive health claims are concerned. According to the Health Protection Inspection, producers of claims are inventive in using scientific information and this makes it very difficult to prove whether a claim is legally true or not.

E. MEANS OF COMMUNICATION

In general, the Dutch Commodities Act and its relevant Decrees apply to 'dealing' in foodstuffs and non-foodstuffs and make no distinction between the use of nutritional and health claims in advertising or in labelling. The application of the regulations is independent from the medium used, although it has to be said that the 'Commodities Act' does not refer to the 'Advertising Code', which specifically deals with misleading advertising.

The fact that claims from other countries can easily appear on the Internet is considered rather a practical than a legal problem. Claims on the Internet fall, like any other nutritional and health claims, under the provisions of the Commodities Act. And also the testing procedure of the Code of Practice makes no difference between communication means.

F. CONSUMER PROTECTION

Borderline cases between positive health claims and medical claims may lead to a potential lack of consumer protection in The Netherlands since it is difficult to prove whether this type of health claim is misleading or not. According to the Dutch Consumer association, the EU could play an important role. However, it has to be said that steering the issue at EU level would require further information on the way in which all the Member States deal with substantiating of claims.

G. BARRIERS TO TRADE

It is said that potential trade barriers are caused by differences in the interpretation and substantiating of claims between the Member States of the European Union. A recommendation by the Dutch Nutrition Centre to counterbalance these differences is to initiate and facilitate a similar instrument as the Dutch Code of Practice Health Benefits 1998 at European Union level. Panels that are testing claims in accordance

this procedure should then consist of independent academic specialists from different Member States. However, this implies that cultural differences would first have to be overcome. This could take some time.

The EU could also play a role in initiating a common sanctioning system in all the Member States. This solution would have the benefit of overcoming both potential trade barriers and potential lack of consumer protection.

H. CASE LAW

There is no important case law in The Netherlands on nutritional claims, while no case law at all exists on ethical claims. Regarding health claims, there is one case judged by a civil court in The Netherlands: The *Nimm-2 case*, on a health claim for sweeteners.

Talks with people from the Inspection Health Protection indicated that a warrant had been given a maximum of ten times following infringement of Article 19 of the Commodities Act. Until now, it has never come to prosecution. In 50 cases, advertisers have been pointed at a possible infringement of the Articles 19 and 20 of the Commodities Act, followed by a discussion with the advertiser. According to the Inspection, this method has a preventive function. Criminal verification of advertising regulations is in general not very effective, partly because of difficulties regarding the burden of proof.

Real verification is taking place through complaints at the Advertising Code Committee. The following 3 cases that have been put before the Advertising Standard Committee are worthwhile mentioning because of the great impact of the verdicts: *Decision 26.10.1994* (see Annex 9), *Decision 18.12.1995* (see Annex 10) and *Decision 02.07.1996* (see Annex 11). The above mentioned cases show that it is not the Health Protection Inspection, but the Advertising Code Committee that plays an important role in more precisely defining borderline cases concerning health claims. It is this Inspection that fills the legal gap wherever there could be a lack of consumer protection.

I. STAKEHOLDER ANALYSIS

In general, whilst all parties concerned in The Netherlands are content with the way nutritional claims are regulated, they underline the importance of the voluntary codes, in particular regarding health claims. The issue of ethical claims has received less attention by the main actors in The Netherlands. Most parties agree that future developments regarding health and ethical claims should be co-ordinated at EU level. However, their approach to the issue differs.

In conclusion, the positions of the main stakeholders are:

1. Government Authorities

- On nutritional claims, the Dutch public authorities see no need for review.

- On health claims, the Dutch public authorities do not formally support the existing voluntary codes of practice and labelling schemes. However, informally the Ministry of Health and the Health Protection Inspection are positive about both codes. It has to be said that the functioning of the Code of practice Health Benefits 1998 still has to prove itself. The public authorities would like to see a regulatory system, including all the codes. They have already started discussing this issue with the parties concerned. However, it is clear that it will not be easy to find a solution, which meets the requirements of all parties concerned. The Health Protection Inspection feels that the verification system of claims in The Netherlands does not function satisfactorily as far as positive health claims are concerned. According to the Health Protection Inspection, producers of claims are inventive in using scientific information. This makes it very difficult to prove whether a claim is legally true or not. They would welcome EU involvement. However, they do not know exactly what action the EU should take.

- On ethical claims, there is no formal policy. The Ministry of Economic Affairs has just started looking into consumer concerns, which might generate some information on public opinion about ethical claims.

2. Consumer Organisations

- According to the Dutch Consumer Association, the EU could play a general role in the verification of borderline cases between positive *health claims* and *medical claims*. The Association points out, however, that steering the issue at European Union level would require further information on the way all the Member States deal with substantiating of claims.

3. Industry

- On nutritional claims, the Dutch Foodstuffs Industry has no substantial comments.

- On health claims, industry feels that a clearer definition could cover borderline cases in the subtle field between positive health claims and medical claims. The industry considers that, under the conditions of the voluntary instruments in place, the Dutch Commodities Act should not prohibit health claims aimed at preventing human diseases. Industry feels that this type of so-called effect claims could be captured under a code of practice, eventually at EU level.

- On ethical claims, industry has no particular position apart from a preference for self-regulation.

- In conclusion, we would surmise that future developments in The Netherlands regarding claims could require EU co-ordination. This is particularly the case with regard to the borderline cases between positive health claims and medical claims. There is also a need for a better integration of ethical claims and codes into the policy field to ensure optimum consumer protection.

* * *

II. MEMBER STATE POLICY

In good Dutch tradition, claims policy in The Netherlands is the result of consultation with all the parties concerned. As far as nutritional and health claims are concerned, these consultations are expressed through the 'Regular Deliberation Commodities Act' forum. Here both public authorities and consumers and industry are represented. Other parties concerned, such as nutritionists and retailers, are closely involved in the deliberations of this forum.

A. DEFINITIONS OF CLAIMS

1. Nutritional Claims

The definition of nutritional claims is provided in article 1, paragraph 1.f of the Dutch *Commodities Act Decree on Nutrition Labelling of Foodstuffs* ("Warenwetbesluit Voedingswaarde-informatie Levensmiddelen", Decree of 07 September 1993, Stb. 1993, 483, as amended by Decree of 15 January 1997, Stb. 1997, 20, (see Annex 1), implementing Directive 90/496/EEC concerning Nutrition Labelling. The definition is the same as the one used in Directive 90/496/EEC.

In Article 1, paragraph 1.f of the above mentioned Decree it reads: 'Any advertising message that is not part of a collective advertising campaign, and any message which states, suggests or implies that a foodstuffs as far as the energetic value or the presence of nutrients is concerned, has particular qualitative or quantitative nutritional properties, as long as these kind of messages are not prescribed in or in virtue of any legal regulation".

Everything falling under the definition of nutritional claims, in conformity with Directive 90/496/EEC, is considered to be a nutritional claim. The explanation of 'nutrition labelling' and 'nutrition claims' are essentially the same. Claims related to nutrition but which do not concern the nutritional value, as such do **not** fall under this definition. On these, the rules, with respect to the prohibition on the use of misleading claims and the use of medical claims, are applied.

Definitions of protein, carbohydrate, sugars, fats, saturates, monounsaturates, polyunsaterates and 'average value' are the same as the Directive 90/496/EEC. In addition, the Dutch legislation includes 'polyols' (sweeteners), 'salt' and 'content' (quantity). There is no definition of 'fibre'; however, a method of analysis for the determination of the content of soluble and insoluble fibre is laid down (the enzymic-gravimetric method according to Asp et al).

2. Health Claims

Dutch law does not contain any definition of health claims. Before discussing the generally accepted definition of health claims in The Netherlands, it is necessary to clarify the legal distinction between foodstuffs, health products and medicines.

Foodstuffs are considered to be edible items and drinking stuffs in terms of the Dutch *Commodities Act* ('Warenwet', Act of 28 December 1935, Stb. 1935, 793, most recently amended by Act of 06 November 1997, Stb. 1997, 510 (see Annex 2). This

Act does not provide for a definition of foodstuffs (in general, everything that is taken orally). However, it defines commodities as food products, including masticate preparations, others than tobacco, and drink products, as well as other stirring stuffs. These two notions do not have the same meaning. Not all food and drink products are considered to be foodstuffs.

Health products are not defined as such in the Commodities Act. They may be partly considered food and drink products as meant in Article 19, paragraph 1.a of the Commodities Act and partly commodities, not being food and drink products as meant in Article 19, paragraph 1.b of the Commodities Act. According to Article 1.c of the Dutch Health Products Code ('Code Gezondheidsproducten'), they are: 'Products either in a pharmaceutical form and with a pharmaceutical character or for which a primary function related to health is being claimed, without making them a medicine. Health products are not supposed to be used as medicine and, in principle, do fall under the Commodities Act.

The Dutch Act on Medicine Provision ('Wet op de Geneesmiddelenvoorziening') defines under Article 1, paragraph 1.e, medicines as 'substance or compositions of substances, which are either meant to be used or to be marked somehow or recommended as being appropriate for: 1. curing, alleviating or preventing a kind of affection, disease, symptom, pain, wound or infirmity of man, 2. recovering, improving or altering of the functioning of human organs, 3. diagnosing the medical case by administration of or application on man'.

Bearing this distinction in mind, the Dutch regulatory practice defines health claims affecting human health as "claims that state, suggest or make come true that a **commodity** would possess special qualities with regard to improving or maintaining the health of the user."

It should be underlined that medical claims - claims that contain a direct connection or a suggestion regarding possible diseases - are forbidden for foodstuffs under Article 19, paragraph 1.a (marketing) and Article 20, paragraph 2.a (advertising) of the Commodities Act. In addition, the Dutch Commodities Act (Article 19, paragraph 1.b and Article 20, paragraph 2.b) provides for a general prohibition to market or advertise commodities in a misleading manner and, therefore, endangering human safety or health. Article 19 of the Dutch Commodities Act is the implementation of Article 2, paragraph 1.b of Labelling Directive 79/112/EEC.

3. Ethical Claims

Dutch legislation does not contain any definition of ethical claims.

B. LEGISLATION IN PLACE

1. Nutritional Claims

Directive 90/496/EEC on Nutrition Labelling of Foodstuffs has been implemented in The Netherlands via the *Commodities Act Decree on Nutrition Labelling of Foodstuffs* ("Warenwetbesluit Voedingswaarde-informatie Levensmiddelen") (see Annex 1). Rules and safeguards with respect to nutritional claims may be found under Article 8

of this Decree. The Decree relates to food and drinks products for delivery to the ultimate consumer and also to mass caterers. Natural mineral water and other types of water for human consumption are not covered by the Decree. Neither are food and drink products that are mainly intended to provide certain nutrients.

Other relevant legislation for nutritional claims is the *Commodity Act Decree on Products for Particular Nutritional Uses* ('Warenwetbesluit Produkten voor bijzondere voeding', Decree of 16 April 1992, Stb. 1992, 222, most recently amended by Decree of 23 January 1998, Stb. 1998, 96) (see Annex 3) and the *Commodity Act Decree on the Addition of Micro-nutrients to Foodstuffs* ('Warenwetbesluit Toevoeging micro-voedingsstoffen aan levensmiddelen, Decree of 24 June 1996, Stb. 1996, 311, as amended by Decree of 23 April 1998, Stb. 1998, 255) (see Annex 4).

The Decree on Products for Particular Nutritional Uses covers the same products as are designated in Directive 89/398/EEC on this subject. Such foods are allowed to be labelled with the description 'dietetic' or 'dietary' and if necessary in conjunction with other terms or designations that relate to their suitability for particular dietary needs. Other labelling requirements are as laid down in the EC Directive on this class of products.

2. Health Claims

The relevant parts of Directive 79/112/EEC on the Labelling of Foodstuffs dealing with health claims have been implemented in The Netherlands via the *Commodities Act* (Warenwet, see Annex 2).

The *Commodity Act Decree on Products for Particular Nutritional Uses* ('Warenwetbesluit Produkten voor bijzondere voeding', see Annex 3) also contains some provisions regarding specific health claims.

Directive 84/450/EEC on Misleading Advertising and Directive 89/552/EEC on Television Broadcasting have been implemented in The Netherlands via the Dutch Civil Code ('Burgelijk Wetboek 6', Article 194-196, see Annex 5) and the Dutch Media Act ('Mediawet), which provides for the issue to be dealt with by the self-regulatory Dutch Advertising Code ('Nederlandse Reclame Code', See Annex 6).

3. Ethical Claims

There is no specific legislation regarding ethical claims. Nevertheless, the relevant articles from the Dutch Civil Code and the general guidelines under Part I of the Dutch Advertising Code that stipulate that advertisements must not be misleading or untrue are applicable to ethical claims. In particular, the rules in this section stipulating that advertising must not be gratuitously offensive or contrary to good taste and common decency, refer to ethical claims.

C. EXISTING PROHIBITIONS, RESTRICTIONS AND EXEMPTIONS

1. Nutritional Claims

a. Prohibitions

Under Article 2 of the *Commodities Act Decree on Nutrition Labelling of Foodstuffs* ("Warenwetbesluit Voedingswaarde-informatie levensmiddelen", see Annex 1), it is prohibited to market any food or drink product without taking into consideration the rules referred to in or in virtue of this Decree. This applies for messages or presentations when nutritional labelling or a nutritional claim is being used.

Goods not belonging to one of the categories of foodstuff for which further more specific rules may be laid down, must be registered with the authorities, with a sample label, before they are brought onto the market for the first time.

b. Restrictions

Under Article 3, paragraph 1 of the 'Decree on the Nutritional Labelling of Foodstuffs', detailed requirements are given concerning the only statements that may be made in relation to the energy or nutrient content of food.

In the above mentioned Decree, Article 8 provides for rules to be taken into consideration for other nutritional claims on foods: energy claims, sugar claims, protein claims, fat claims, fatty acid claims, dietary fibre claims, sodium claims, vitamin claims, mineral claims and micro-nutrients in general.

Article 5 of the Decree on the Addition of Micro-nutrients to Foodstuffs provides for the addition to food of certain named vitamins and minerals. Food containing such additions is classified as 'fortified food or drink products'. However, the main purpose of the product is not the supply of micro-nutrients. Nutrition labelling must be declared on fortified foodstuffs (Article 7, Decree on the Addition of Micro-nutrients to Foodstuffs). A declaration of the added micro-nutrients must also be made for fortified foodstuffs that are not restored or substitution products (Article 8, paragraphs 2 and 3 of the same Decree). Claims concerning the nutritional value of 'fortified foods or drinks' may be made only in relation to micro-nutrients naturally present (Article 8, paragraph 1 of the same Decree).

Statements relating to the fat content of certain foods, such as cheese, yogurt or spreadable fats, are provided for in Dutch legislation, but these are not, strictly speaking, nutrition claims.

c. Exemptions

Nutritional labelling is not compulsory under the *Commodities Act Decree on Nutrition Labelling of Foodstuffs* ("Warenwetbesluit Voedingswaarde-informatie Levensmiddelen", see Annex 1). However, once a nutritional claim is made on the label, nutrition labelling as described in the Decree must take place. Information to be supplied, form of declaration, basis for declared values and calculation of energy

value are as shown in Directive 90/496/EEC. There are no provisions covering non-pre-packaged foodstuffs packaged at the point of sale.

2. Health Claims

a. Prohibitions

In line with the status of a generally accepted definition of health claims on foodstuffs, no further prohibitions are mentioned under Dutch law.

b. Restrictions

See again the definition of health claims as mentioned before.

c. Exemptions

Article 19, paragraph 3 and 20 and paragraph 4, of the 'Commodities Act' provide for the possibility to decide on messages or presentations that are considered to be messages or presentations, under Article 19, paragraph 1 or Article 20, paragraph 2 of the Act. This possibility, however, needs to be approved by a Ministerial Decision.

3. Ethical Claims

a. Prohibitions

As no specific legislation exists for ethical claims, Articles 194-196 from the Dutch Civil Code Number 6 apply. This aims to protect consumers and competitors from misleading advertising. These rules, also described as the 'Misleading Advertising Act', consist of a specification of illegal offences (Civil Code Number 6, Article 162). Article 194 provides for a non-exhausting list of announcements that could be considered misleading. This could be the case regarding price, origin or composition of the commodity.

b. Exemptions

As no specific legislation exists for ethical claims, no exemptions are foreseen under Dutch law. Articles 194-196 of the Dutch Civil Code Number 6 only apply to misleading advertising and not, for example, to negative or positive advertising. The latter two forms of unlawful advertising fall under the general unlawful practice rules.

c. Restrictions

Since no specific legislation exists for ethical claims, the general restriction of the above mentioned Articles from the Civil Code apply. They only apply to announcements made while exercising a profession or business. General, ideal and political announcements do not fall under these Articles.

D. POLICY DEVELOPMENTS AND STAKEHOLDERS' POSITIONS

The Dutch public authorities favour the process of coming to common definitions of claims at EU level, through the guidelines as given by the Codex Alimentarius.

1. Nutritional Claims

The nutrition policy as implemented by the Dutch authorities (Ministry of Health, Welfare and Sports) is based on two basic assumptions:

- Guaranteeing an adequate level of food safety; and
- Encouraging good nutritional behaviour.

The policy states that a right use of nutritional claims can contribute to honouring these assumptions. For the authorities, this means ensuring honest, transparent information and correct implementation of the principles set out in relevant EU Directives, in particular 79/112/EEC on Labelling and 90/496/EEC on Nutritional Labelling.

The starting point for this is the Dutch 'Balanced Diet Guidelines', which reflect the state of science in this field. These guidelines should be taken as far as possible into consideration when applying the rules for nutritional claims. That is to say that nutritional claims regarding a product should relate to a property that is nutritionally relevant. On the basis of this approach, a number of claims groups have been regulated.

Policy thinking is that current legislation on nutritional claims is satisfactory and that a restriction or extension of possibilities should take place on the basis of the nutritional goals that are being pursued.

The Dutch regulatory practice regarding nutritional claims goes further than the EU Directives and is considered satisfactory by the parties concerned. Apart from some fine-tuning regarding optional rules, there seems to be no need for adaptation. The only policy developments taking place in this field concern different types of fats.

2. Health Claims

Dutch policy and regulatory practice regarding health claims allows this type of claims for foodstuffs, providing that they are true and not misleading. It is, however, forbidden to allude to medical claims. This way of policy thinking is based on the idea that one should not profit by making consumers anxious about diseases. It is worthwhile noting that currently there is insufficient scientific data available to be able to determine whether the use of health claims, unlike the use of nutritional claims, can be to the advantage of the consumer.

In general, all parties concerned feel that current policy regarding health claims is satisfactory: the public authorities playing a supporting, but modest, role thereby leaving room for self-regulation. There seems to be no need in The Netherlands for new legislation regarding health claims at national level but most of the parties concerned do see the need for future legislative developments to be arranged at the

EU level. Some parties, such as retailers, advocate, in particular, a faster decision-making process to approve health claims at national level and to have a negative list of health claims at EU level.

Some policy developments might be expected relating to borderline cases, which exist between positive health claims and medical claims (including claims regarding cholesterol). There is a general view that there is a 'grey area' between these two types of claims, which is not covered by legislation. The issue has already been the subject of discussion during a long time and touches upon the reach of prevention, which is now limited to vaccines.

In particular, the Dutch foodstuffs industry considers this issue a priority and feels that, under the conditions of the voluntary instruments in place, the Commodity Act should not prohibit health claims aimed at preventing human diseases. Industry feels that this type of so-called effect claim could be captured under a code of practice. The problem is that adaptation of the law would require further information on the substantiating of claims and whilst no academic data is available, this information is only available to industry. According to the Dutch Consumer Association, the EU could play a general role here. However, steering the issue at European Union level would require further information on the way in which all the Member States deal with the substantiating of claims.

It is worth noting here that over the past years another thorough discussion has been taking place in The Netherlands regarding functional foods, novel foods and food supplements and the verification problem of claims in this field. In fact, it has been voluntarily agreed to substantiate claims on vitamin supplements to margarine, while a similar agreement for claims on herb preparations is in the pipeline, taking the issue out of the scope of the current legislation.

Furthermore, it should be underlined that the Dutch Parliament is currently discussing deregulation of the 'Commodities Act'. However, this is without consequence for the regulatory practice regarding health claims in The Netherlands. This practice is under permanent discussion by all parties concerned in the 'Regular Deliberation Commodity Act' platform.

3. Ethical Claims

At the moment, there is no specific Dutch policy in the field of ethical claims. In The Netherlands, the Ministry of Economic Affairs and the Ministry of Agriculture are responsible for social and animal welfare claims respectively.

Currently, a project group under the Ministry of Economic Affairs is looking into consumer concerns. This might provide information on public opinion towards ethical claims. For the Ministry of Agriculture, ethics in general play a role in its policy preparation regarding guaranteeing animal welfare and food safety.

The only idea of the public authorities (Ministries of Economic Affairs and Agriculture) is to divide this type of claims according to their specific character and deal with them on a separate basis.

F. BARRIERS TO TRADE AND LACK OF CONSUMER PROTECTION

1. Nutritional Claims

It seems generally accepted that regarding nutritional claims, there are no real problems relating to barriers to trade or lack of consumer protection.

2. Health Claims

Furthermore, as regards health claims, it seems generally accepted that there are no significant problems relating to barriers to trade or lack of consumer protection. Nevertheless, it is worthwhile noting the following:

- The Dutch legislation on health claims is considered quite severe;
- On 4 June 1999, the Dutch Parliament adopted a law, making it compulsory for health claims to be made in the Dutch language;
- Barriers to trade could be caused by the above mentioned 'grey area' between positive health claims and medical claims, since it is not fully covered by legislation. This situation could also affect consumer protection.

3. Ethical Claims

In spite of the absence of any specific legislation on ethical claims, none of the parties concerned in The Netherlands felt that there were barriers to trade or lack of consumer protection.

III. VOLUNTARY INSTRUMENTS USED

A. VOLUNTARY INSTRUMENTS IN PLACE

1. Nutritional Claims

No specific voluntary instruments exist in The Netherlands for nutritional claims.

2. Health Claims

In The Netherlands, there are three important voluntary instruments covering the field of health claims.

- The *Dutch Advertising Code* ('Nederlandse Reclame Code', see Annex 6);
- The *Code of practice assessing the scientific evidence for Health benefits stated in Health claims on food and drink products 1998* ('Gedragscode wetenschappelijke onderbouwing Gezondheidseffecten ten behoeve van Gezondheidsclaims voor eet- en drinkwaren 1998, see Annex 7);
- The *KOAG/KAG Code for the advertisement of Health products*' ('KOAG/KAG Code voor de aanprijzing van Gezondheidsproducten, see Annex 8).

a. The Dutch Advertising Code

The Dutch Advertising Code contains rules which, in principle, apply to all three types of claims. It is divided into a General section and a Special Section. In addition to the General Code, certain specific codes have been added. These were drafted in co-operation with self-regulatory bodies, such as the Foundation for the Responsible use of Alcohol ('Stichting Verantwoord Alcoholgebruik'), the Advertising Steering group Foundation ('Stichting Stuurgroep Reclame'), which are the Dutch advertising tripartite, and the industries concerned (e.g. tobacco, direct mail or motor industry).

Part I of the Dutch Advertising Code contain general guidelines that stipulate, inter alia, that advertisements must **not be misleading or untrue**. This section also contains a number of rules based on subjective criteria, one of which stipulates that advertising must **not be gratuitously offensive or contrary to good taste and common decency**. Part II of the Code contains Special Guidelines and related rules for specific products and services. These rules supplement the general provisions of the Code and are as follows:

- Rules on advertising for medicines and homeopathic products, which require pre-clearance by the KOAG and the Council for the Advertising of non-prescription Medicines);
- Rules on advertisements for training courses;
- Rules on advertisements for competitions;
- Rules on advertisements for loans, investments and property;
- Rules on advertisements for home working;
- The Code for Alcoholic Beverages;
- The Code on Letterbox Advertising, House Sampling and Direct Response Advertising;
- The Code on the Distribution of Unaddressed Advertising Leaflets;
- The Advertising Code for Casino Games;
- The Environmental Advertising Code;
- The Code for Passenger Cars;
- The Advertising Code for Tobacco Products;
- The Sweepstakes Codes; and
- The Confectionary Code.

b. The Code of practice assessing the scientific evidence for Health benefits stated in Health claims on food and drink products 1998

The Code of practice is aimed at getting evidence for health claims on foodstuffs to be scientifically founded and reported. This Code was initiated by the Dutch Nutrition Centre ('Voedingscentrum'), which is an independent non-profit organisation consisting of professionals in the food sector. The Nutrition Centre is mainly financed by the Ministries of Agriculture and Health and its Advisory Council consists of representatives from science, trade and industry and several independent groups (including the Central Office for Foodstuffs Trade, the Consumer Association and the Dutch Foodstuffs Industry). This organization facilitates the testing procedure, by bringing together a panel of independent academic specialists. The disadvantage of

the Code of practice is that it concerns a heavy and expensive procedure, whereby the addressee has to go through prescribed stages.

The Code has only been in force since April 1998 and so far there have been no concrete cases. Although industry is a signatory of the Conduct Code, it is still uneasy about the testing procedure. Nevertheless, three products are in the pipeline and, in the future, one can expect several margarine producers to make use of the testing procedure with a view to having their claims confirmed. The functioning of the Code will be evaluated in two years time, with a view to attuning it to safety assessment methods.

c. The KOAG/KAG Code for the advertisement of Health products

The highly regarded KOAG/KAG Code is mainly aimed at preventing the use of medical claims on health products. The Code was initiated by the Dutch Verification Council ('Keuringsraad'), a self-regulatory body for the public advertising of medicinal products (KOAG), natural remedies and other health products (KAG). It has now been in place for many years.

Under the guidelines of its Code, KOAG/KAG pre-vets all public advertising for non-prescription products and homeopathic medicines and for health products. KOAG/KAG is, therefore, competent for the public advertising of all medicinal products (including foodstuffs) whose use is recommended for treating, alleviating or preventing disease, illness, symptoms, pains, injury or deficiency. KOAG/KAG does not handle complaints.

3. Ethical Claims

There currently exist two specific labelling schemes regarding ethical claims. A further two are being developed.

- The Max Havelaar Trademark ('Max Havelaar Keurmerk');
- The Fair Trade Charter for Garments;
- The Fair Trade Treaty for Clothes Foundation ('Stichting Eerlijke Handels Handvest voor Kleding'); and
- The Conduct Code for the Coffee-sector.

a. The Max Havelaar Trademark ('Max Havelaar Keurmerk')

The Max Havelaar Trademark is an instrument to help farmers in developing countries to improve their economic situation. It guarantees these farmers higher revenues and, therefore, offers better opportunities. The 'Max Havelaar Foundation' is the certifying institution controlling the Max Havelaar trademark. The trademark, with 32 licensees in the field of coffee, bananas, tea and cacao, is one of the best known idealist ones in The Netherlands. It was initiated because of the need among producers. The idea behind the trademark is to inform consumers.

b. The Fair Trade Charter for Garments

The 'Fair Trade Charter for Garments' is a code of conduct for all retailers selling clothes in The Netherlands and is part of the 'Clean Clothes Campaign'. This Campaign in The Netherlands is an appeal to consumers to be more conscious when buying clothes, and to support demands the campaign is making to retail companies. This is done by supplying information, by giving lectures, participating in discussions and holding pickets and other street-actions to draw attention to the conditions under which garments are produced in developing countries.

c. The Fair Trade Charter for Clothes Foundation ('Stichting Eerlijke Handels Handvest voor Kleding')

The Dutch organisation Fenecom is working on a trademark for the clothes-sector in The Netherlands under the name Fair Trade Charter for Clothes Foundation ('Stichting Eerlijke Handels Handvest voor Kleding'). The aim of the trademark is to support the International Labour Organisation (ILO) rules. In the current roll-out phase, Dutch companies can apply for membership.

d. The Conduct Code for the Coffee-sector

Currently, the Dutch Fair Trade Organisation is initiating a Conduct Code for the coffee-sector in The Netherlands, while at the same time asking the public authorities for a more active policy in this field.

B. DEFINITIONS USED IN THE VOLUNTARY INSTRUMENTS

1. Nutritional Claims

No voluntary instruments for nutritional claims exist.

2. Health Claims

Both the Dutch Advertising Code and the Code of practice, as well as the KOAG/KAG Code use the same generally accepted definition for health claims. The Dutch regulatory practice defines health claims affecting human health usually as "claims that state, suggest or make come true that a **commodity** would possess special qualities with regard to improving or maintaining the health of the user' (see chapter II, paragraph A.2).

As far as the Code of practice is concerned, the panel of independent academic specialists is doing its tests on the basis of 3 criteria that cover:

- Quality of the scientific substantiating;
- The relevance for the target group;
- Whether the health effect is opposed to healthy food.

The actual application of these criteria is very precise, since it concerns a case-by-case approach.

3. Ethical Claims

The two labelling schemes in place in The Netherlands do not use any specific definition of ethical claims. However, they implicitly use the notion of ethics in their goals.

C. EXISTING PROHIBITIONS, RESTRICTIONS AND EXEMPTIONS

1. Nutritional Claims

Not applicable.

2. Health Claims

The Dutch Advertising Code does not specifically refer to any claims; however, Part II of the Code contains Special Guidelines and the related rules for specific products and services.

- For beverages, a notification obligation is in force (tobacco, alcohol) and in a number of cases an absolute prohibition to advertise for these products (prohibition of radio and television advertising for tobacco, general prohibition of advertising for drugs).
- Regarding alcohol and sweets a prohibition of health claims is in force.
- As far as pharmaceutical (vitamin preparations, minerals), cosmetic and miracle products are concerned, a general prohibition is in force of misleading advertising and, therefore, endangering the consumer's health. It is absolutely prohibited to advertise for medicines and it is also prohibited to use medical claims for foodstuffs.

The main restriction for health claims of the Code of practice is the fact that it cannot force any sanctions. The way of sanctioning is either positive or negative publicity following a decision by the panel of independent academic specialist. According to the Dutch Nutrition Centre, the EU could play a role in initiating a common sanctioning system in all the Member States.

The limitation of the KOAG/KAG Code is that it basically applies to health products.

3. Ethical Claims

All the labelling schemes mentioned before, use ethical claims either in the field of worker protection or fair trade.

D. VOLUNTARY INSTRUMENTS ACCEPTED/RECOGNISED BY THE AUTHORITIES

1. Nutritional Claims

No voluntary instruments for nutritional claims exist.

2. Health Claims

Formally, the public authorities do not support these three instruments. However, informally the Ministry of Health, as well as the Health Protection Inspection is positive about both codes, although it has to be said that the functioning of the Code of practice still has to prove itself.

What the public authorities would like to see is a regulatory system, including these three codes. They have already started discussing this issue with the parties concerned. However, it is clear that it will not be easy to find a solution, which meets the requirements of all parties concerned.

3. Ethical Claims

Formally, the public authorities do not support the labelling schemes. However, informally they are positive about them.

IV. VERIFICATION SYSTEMS

A. CRITERIA FOR SUBSTANTIATING CLAIMS

1. Nutritional Claims

The Dutch Decree on Nutritional Labelling of Foodstuffs does not provide for any criteria for substantiating nutritional claims.

2. Health Claims

Whereas the Dutch Commodities Act does not provide for specific criteria for substantiating health claims, with the coming into force of the Code of practice assessing the scientific evidence for Health benefits stated in Health claims on food and drink products 1998, scientific evidence for a health benefit is assessed using the following formula of 3 criteria:

- *The quality of the scientific evidence*: The evidence must be based on relevant scientific data on human subjects; the evidence must apply to a product or product group; and the evidence must be reproduced.

- *Relevance to the target population*: The data must concern normal use (consumed quantities) by the target population and the product must carry health benefit relevant to that target group.

- *Must not clash with dietary guidelines:* The health benefit must not clash with dietary guidelines, as laid down in publications by the former Nutrition Council and the Health Council and in similar publications.

3. Ethical Claims

As far as ethical claims are concerned, no specific criteria for substantiating nutritional claims exist.

B. LEGAL/ADMINISTRATIVE SYSTEMS FOR VERIFYING CLAIMS

1. Pre-Clearance Rules/ Guidelines

No pre-clearance rules exist in The Netherlands. Pre-clearance is considered censorship and is, therefore, not applied.

2. Post-Clearance Rules/ Guidelines

The system for verifying claims in The Netherlands is twofold:

- On the one hand, there is the Health Protection Inspection/Commodities and Veterinary surgeons ("Inspectie Gezondheidsbescherming/Waren en Veterinairen"), with whom one can lodge a complaint or that can initiate a post-clearance procedure to prove that a particular claim is untrue.

- On the other hand, there is the Advertising Standard Committee ("Reclame Code Commissie"), which is following up all types of claims and can ask anyone using a claim to prove that a particular claim is true.

The twofold verification system of claims in The Netherlands has not been functioning to the satisfaction of all parties concerned and could cause barriers to trade or lack of consumer protection as far as positive health claims are concerned. According to the Health Protection Inspection, producers of claims are inventive in using scientific information and this makes it very difficult to prove whether a claim is legally untrue or not.

a. Legal procedure

Unlawful nutritional and health claims are viewed as infringements of the regulations concerned in the 'Commodities Act'. Complaints about non-compliance can be lodged to the Health Protection Inspection, which is appointed as (market) supervisor. The possibility for lodging a complaint is not limited to certain groups or persons.

Non-compliance with specific labelling requirements and/or specific limitations on advertising are legally regarded as misleading advertising, when it concerns non-compliance of specific labelling regulations and/or specific restrictions with regard to advertising under article 19 of the 'Commodities Act' regarding medical claims and article 20, first indent of the 'Commodities Act', article 29 of the 'Commodities Act Decree on Labelling Foodstuffs' regarding misleading recommendations and article 8 of the 'Commodities Act Decision Nutritional Information Foodstuffs' regarding nutritional claims.

The number of cases regarding claims dealt with by the Health Protection Inspection has been relatively small. It concerns both nutritional and health claims as far as they

are considered to endanger public health. Although legally spoken, KOAG/KAG has nothing to do with the Health Protection Inspection, these two organisations do consult each other informally twice a year.

b. Self-regulatory procedure

Next to this, relevant complaints can also be brought before the Advertising Standard Committee, which has been set up by the Advertising Code Foundation ('Stichting Reclame Code') that unites consumers, advertisers and the media. The Advertising Standard Committee is an independent private body and not a legal court in the strict sense of the word. It has the remit of assessing compliance with the Dutch Advertising Code ('Nederlandse Reclame Code') of advertisements against which complaints are made. In the event of an appeal against the Committee's ruling, the matter is referred to the Appeals Board ('College van Beroep'), which issues a definite ruling.

The Advertising Code Committee consists of four independently-operating committees, each composed of five members. The appropriate committee is determined by the media, in which the advertisement appeared. Each committee is chaired by an independent legal expert. The other four members are appointed by the Foundation's member organisations, but act in an independent capacity. The Appeal Board is organised on the same media-specific basis as the Advertising Code Committee.

The Advertising Code Committee does not work with a pre-clearance system and although it is empowered to monitor advertisements on its own initiative, in practice it rarely does so, because monitoring is considered unacceptably arbitrary. The three broadcasting bodies and individual commercial broadcasters, however, examine all broadcast advertising before transmission for compliance with the Advertising Code. Any member of the public can lodge a written complaint with the Secretariat of the Committee, clearly outlining to which advertisement the complaint relates, why the complainant considers the advertisement to be in breach of the Dutch Advertising Code and, where possible, enclosing a copy of the advertisement in question.

Upon receipt of the complaint, an initial assessment is carried out by the Chairman and the Secretariat, to determine whether the complaint should be considered by the Committee. If it decides that it should not, the Committee's Chairman informs the complainant accordingly, in the form of a rejection - an appeal against which can be lodged with the plenary Advertising Code Committee. Complaints which are judged suitable for consideration by the Committee are subject to the following procedure:

- Firstly, the advertiser is provided with a copy of the complaint for his response, a copy of which is then forwarded to the complainant;
- A hearing is then arranged at the offices of the Advertising Code Foundation, where the parties are invited to elaborate on their respective points of view;
- The Advertising Code Committee issues a written ruling within a few weeks of this hearing.
- The loser has the option of lodging an appeal with the Appeals Board. Four decisions are open to the Appeals Board: The appeal is well-founded and the decision of the Committee is annulled; the appeal is unfounded and the decision of the Committee is confirmed; the appeal is partially founded and the decision of the

Committee is amended; and the case is referred back to the Committee for reconsideration.

Complaints can be submitted and handed free of charge, except in cases where a complaint is filed on behalf of a professional body or company, in which case a fee of HFl 500 (approx. EUR 227) is charged. Up to now, only a limited number of cases have been put before the Advertising Standard Committee. Most of the cases this Committee has been dealing with concern health claims and, in particular, borderline cases. This shows that there is a growing tendency in The Netherlands to use forms of medical claims.

C. LEGAL PERSONS ENTITLED TO TAKE LEGAL ACTION

As far as the Health Protection Inspection is concerned, the possibility for lodging a complaint is not limited to certain groups or persons.

Any member of the public can lodge a written complaint with the Secretariat of the Advertising Code Committee, clearly outlining to which advertisement the complaint relates, why the complainant considers the advertisement to be in breach of the Dutch Advertising Code and, where possible, enclosing a copy of the advertisement in question.

D. BURDEN OF PROOF

1. Burden of proof

Whereas the Health Protection Inspection can initiate a post-clearance procedure (notifications of claims are only obligatory under the 'Directives for Special Foods') to prove that a particular claim is untrue, the Advertising Code Committee can ask anyone using a claim to prove themselves that a particular claim is true. In its judgements, the Advertising Code Committee does not yet refer to the Code of practice assessing the scientific evidence for Health benefits stated in Health claims on food and drink products 1998.

E. APPLICABLE PENALTIES

As far as the procedure of the Health Protection Inspection is concerned, infringement of the rules on claims is considered an economic offence and is to be submitted to the Public Prosecutor, who will notify the party concerned by means of a warrant. A first infringement will be penalised by a settlement consisting of a relatively little amount of money. In case of a second breach of the rules and when a claim is considered to endanger public health, the Public Prosecutor can eventually decide to take a particular product off the market. The idea is to change the provisions for a first infringement into a system of public fines, whereby the whole procedure would be dealt with by the Health Protection Inspection. A second breach would then still follow the current legal procedure.

Regarding the procedure of the Advertising Code Committee sanctions are being dealt with as follows: If an advertisement is found to infringe the Dutch Advertising Code, the Committee will instruct the advertiser to stop using it in its current form. In the

event of a repeat offence or a serious violation of the Code, the Committee-affiliated media will be instructed to stop publishing the advertisement concerned. The media, who are obligatory members of the Advertising Code Foundation, are required to refuse advertisements against which such a ban has been issued.

Only on the basis of agreements between the Committee and certain sectoral organisations (alcohol, tobacco, gambling and sweepstakes), the Committee is in certain cases empowered to impose sanctions on the advertiser. The Committee can oblige him to reimburse money, promulgate its recommendation amongst the recipients of the advertisements, or publish a corrective statement. Decisions reached by the Advertising Code Committee and the Appeals Board are published every 6 months in a report.

V. CASE LAW

1. Nutritional Claims

There is no important case law in The Netherlands on nutritional claims.

2. Health Claims

The only health claim judged by a civil court in The Netherlands concerns a health claim for sweeteners, the Nimm-2 case. The implicit claim *'They ask for a sweetie, you give them a bit more' combined with 'Nimm-2 the new sweetie with grape-sugar and vitamin C'* was judged to fall under the prohibition of health claims under Article 4 of the Code for Sweeteners. It was judged that in reality the sugar containing sweet stimulated caries and therefore harmed the health of the teeth and the well being of the user. And by referring to a relatively low sugar content, one may not give the impression that the chances for developing caries are relatively small.

Talks with people from the Inspection Health Protection indicated that a warrant had been given a maximum of ten times following infringement of Article 19 of the Commodities Act. Until now, it has never come to prosecution. In 50 cases, advertisers have been pointed at a possible infringement of the Articles 19 and 20 of the Commodities Act, followed by a discussion with the advertiser. The results of these procedures may be found in the annual reports of the Health protection Inspection (The 1998 Report will be available by September 1999). According to the Inspection, this method has a preventive function. Criminal verification of advertising regulations is in general not very effective, partly because of difficulties regarding the burden of proof.

Real verification is taking place through complaints at the Advertising Code Committee. This Committee is in practice the only institution that regularly assesses health claims on the basis of its contents. The following 3 cases that have been put before the Advertising Standard Committee are worthwhile mentioning because of the great impact of the verdicts:

- *Decision of the Advertising Standards Committee, 26.10.1994* (see Annex 9)*:*

1. The decision allowed the claim "A desert that improves your resistance";
2. Product: 'MONA VIFIT', daily based desert;

3. Conclusion of the Committee: The claim is not considered as a medical claim because it is not plausible that the product could be regarded as preventing, treating or healing of illnesses.

- *Decision of the Advertising Standards Committee, 18.12.1995* (see Annex 10)*:*

1. The decision disapproved the claim "Don't catch a cold custard";
2. Product: 'Vat Geen Kou-Vla', dairy based dessert;
3. Conclusion: The claim is considered misleading, because there is no evidence that by consuming this custard one would be protected from catching a cold.

- *Decision of the Advertising Standards Committee, 02.07.1996* (see Annex 11)*:*

1. The decision allowed the claim "Contributes to an appropriate cholesterol level";
2. Product: 'MONA FISIQ', yogurt;
3. Conclusion of the Committee: The claim is not misleading, because the producer has presented scientific evidence, justifying the claimed contribution to reducing the cholesterol level.

The above mentioned cases show that it is not the Health Protection Inspection, but the Advertising Code Committee that plays an important role in more precisely defining borderline cases concerning health claims. It is this Inspection that fills the legal gap wherever there could be a lack of consumer protection.

3. Ethical Claims

There exist no case law regarding ethical claims.

VI. MEANS OF COMMUNICATION

In general, the Dutch Commodities Act and its relevant Decrees apply to dealing in foodstuffs and non-foodstuffs. Dealing is defined as "offering for sale, exposing for sale, selling, delivering or having in store/stock of a commodity". This means that no distinction is made between the use of nutritional and health claims in advertising or in labelling. The application of the regulations is independent from the medium used, although it has to be said that the 'Commodities Act' does not refer to the 'Advertising Code', which specifically deals with misleading advertising.

Since 4 June 1999, there is a requirement in the Dutch legislation for labeling information to be in the Dutch language, as it must be clearly understandable to the purchaser.

The fact that claims from other countries can easily appear on the Internet is considered rather a practical than a legal problem. Claims on the Internet fall, like any other nutritional and health claims, under the provisions of the Commodities Act. And also the testing procedure of the Code of practice makes no difference between communication means.

VII. STATISTICS ON CLAIMS

TNO Report V97.180 concerning project 334304 on consumer acceptance of *health claims* for foodstuffs (see Annex 12).

In 1996, by order of the Ministry of Health, Research Institute *TNO Nutrition* had done a research to consumer acceptance of health claims. Face-to-face interviews were held among 1018 households. The respondents consisted for 82% of women. The objective of the research was the following: 'To get an overview of consumer acceptance of different (types of) nutritional- and health claims for foodstuffs'.

The conclusion of the research is that consumers have a considerable critical attitude towards food additives and accompanying nutritional and health claims. Because of relatively poor nutritional knowledge, the information available cannot always be valued properly. These findings confirm the view that for successfully applying health claims on foodstuffs, it is vital that these claims are comprehensible and reliable, while being supported by solid nutritional information.

VIII. ANNEXES

Annex 1: *Commodities Act Decree on Nutrition Labelling of Foodstuffs* ("Warenwetbesluit Voedingswaarde-informatie Levensmiddelen", Decree of 07 September 1993, Stb. 1993, 483, as amended by Decree of 15 January 1997, Stb. 1997, 20)
Annex 2: *Article 19 and 20 of the Commodities Act* ('Artikel 19 en 20 van de Warenwet', Act of 28 December 1935, Stb. 1935, 793, most recently amended by Act of 06 November 1997, Stb. 1997, 510)
Annex 3: *Commodity Act Decree on Products for Particular Nutritional Uses* ('Warenwetbesluit Produkten voor bijzondere voeding', Decree of 16 April 1992, Stb. 1992, 222, most recently amended by Decree of 23 January 1998, Stb. 1998, 96)
Annex 4: *Commodity Act Decree on the Addition of Micro-nutrients to Foodstuffs* ('Warenwetbesluit Toevoeging micro-voedingsstoffen aan levensmiddelen, Decree of 24 June 1996, Stb. 1996, 311, as amended by Decree of 23 April 1998, Stb. 1998, 255)
Annex 5: *Civil Code – Article 194-196* ('Burgelijk Wetboek 6', Article 194-196)
Annex 6: *Dutch Advertising Code* ('Nederlandse Reclame Code')
Annex 7: *Code of practice assessing the scientific evidence for Health benefits stated in Health claims on food and drink products 1998* ('Gedragscode wetenschappelijke onderbouwing Gezondheidseffecten ten behoeve van Gezondheidsclaims voor eet-en drinkwaren 1998)
Annex 8: *KOAG/KAG Code for the advertisement of Health products*' ('KOAG/KAG Code voor de aanprijzing van Gezondheidsproducten)
Annex 9: *Decision of the Advertising Standards Committee, 26.10.1994,* allowing the claim "A desert that improves your resistance" from product 'MONA VIFIT', a daily based desert
Annex 10: *Decision of the Advertising Standards Committee, 18.12.1995,* disapproved the claim "Don't catch a cold custard" from product 'Vat Geen Kou-Vla', a dairy based dessert

Annex 11: *Decision of the Advertising Standards Committee, 02.07.1996,* allowing the claim "Contributes to an appropriate cholesterol level" from product 'MONA FISIQ', a yogurt
Annex 12: *TNO Report V97.180 concerning project 334304 on consumer acceptance of health claims for foodstuffs* ('TNO Rapport V97.180 van project 334304 aangaande consumentenacceptatie van gezondheidsclaims voor voedingsmiddelen)

IX. DATABASE OF CONTACTS

M. PORTUGAL

I. EXECUTIVE SUMMARY

A. INTRODUCTION

The study was well received by all interested parties in Portugal. A problem with the research undertaken in Portugal was that many respondents were not familiar with the issue of claims and could, therefore, provide only limited information.

B. MEMBER STATE POLICY

1. Nutritional Claims

The definition of a nutritional claim is the same as defined in EU law. The terminology is slightly different, as the word 'claim' has been literally translated as 'declaration'. Portuguese authorities consider the current legislation on nutritional claims to be satisfactory.

2. Health Claims

With regard to health claims, Portugal implemented nearly word by word Directive 79/112. But in addition, further provisions are made under Portuguese law, which somewhat extends the prohibitions of Directive 79/112.

The Portuguese authorities indicated that they had, so far, not reflected on the issue of health claims. No policy initiatives are currently planned.

3. Ethical Claims

There is no legal definition of an ethical claim and no directly relevant legislation. The consumer associations are pressing for the introduction of a mechanism to supervise the use of ethical claims. A proposal has been put forward by the Portuguese Association for Consumer Defence (DEC) for the introduction of a social label. No feedback has so far been given by the authorities on this proposal.

C. VOLUNTARY CODES OF PRACTICE

There do not exist any voluntary codes of practice in Portugal for nutrition, health or ethical claims. Nevertheless, the Portuguese food industry association is currently working on codes of practice for health claims, but these are still at a very early stage.

D. VERIFICATION SYSTEMS

With regard to the criteria for substantiating claims, the only ones that apply are those set out in the law on nutritional labelling and on dietary foods. Those set out under the notification procedure of dietary foods apply.

There exists no pre-vetting in Portugal. A posteriori controls are undertaken by the Directorate General for Surveillance and Control Food, which is attached to the Ministry of Agriculture, and the General Inspectorate of Economic Activities, which is the central service of the Ministry of Commerce. Furthermore, the Consumer Institute, which is a public institution, is in charge of the supervision of the application of the Advertising Code. The competencies of the different administrative authorities sometimes overlap.

The burden of proof lies with the complainant. Nevertheless, the situation is different when the authorities start an investigation. The Advertising Code states that affirmations on the origin, nature, composition, properties and conditions of purchase of advertised goods and services have to be true and these affirmations must be able to be proven at all times before the competent authorities.

Penalties range between 1750 euro and 45000 euro. In addition, the authorities can confiscate the products in question, as well as suspend the commercialisation and sale of the products.

E. MEANS OF COMMUNICATION

There are no differences between the different means of communication with regard to claims or advertising.

F. CONSUMER PROTECTION

The consumer associations indicated that there were only a few identified cases of lack of consumer protection, but which were in their view partly attributable to the lack of means available to inspect products being marketed or crossing borders. Furthermore, the consumer associations felt that existing legislation on health claims did not offer sufficient legal protection to consumers. In particular the absence of clearly defined rules for substantiating claims implies that only if a grave threat to the health of consumers is identified can an investigation to determine the veracity of the claim be started.

The only statistics available from the Portuguese Association of Consumer Defence (DECO) refer to complaints on labelling in general. Most of the cases seem to be related to the fact that labelling was written in languages other than Portuguese, or in the omission or incorrect use of information. These statistics do not provide specific information on claims.

G. TRADE BARRIERS

The authorities consider that there are no significant barriers to trade with regard to health claims, as EU Directive 79/112 is fully applied in Portugal.

The Portuguese food industry association considers that the Portuguese food industry is at a disadvantage, as the Portuguese authorities are, on the one hand, very restrictive in their practice vis-à-vis health claims, but on the other they import far-reaching health claims from other Member States.

H. CASE LAW

No recent court cases exist on either type of claims.

I. STAKEHOLDER ANALYSIS

In general, there has been very little reflection in Portugal on the issue of nutritional and health claims. Overall, nutritional and health claims are considered issues that need to be tackled by the EU. With regard to ethical claims, consumer associations have undertaken some reflection on this issue.

In conclusion, the positions of the main stakeholders are:

1. Government Authorities

- On nutritional claims, the authorities consider current legislation satisfactory.
- On health claims, no policy thinking has yet taken place.

2. Consumers

- Consumers are in favour of clearly defined rules for substantiating claims.

3. Industry

- Industry considers the practice of the Portuguese authorities with regard to health claims too restrictive. Industry is looking towards the EU to create a framework for health claims.
- On ethical claims, consumer associations are in favour of some instruments (either legal or in the form of voluntary instruments) to supervise their use.

*** * ***

II. MEMBER STATE POLICY

A. DEFINITION OF CLAIMS

1. Nutritional Claims

The definition of nutritional claims is provided in article 2, point b) of the Portuguese nutrition labelling decree, determining the conditions that must be observed by the nutrition labelling of foodstuffs (Decree 751/93, see Annex 1):

"b) Nutritional claim: any representation or message used in advertising which states, suggests or implies that a foodstuffs has particular nutrition properties due to the energy or caloric value that it gives or does not give or the nutrients it possesses or does not possess; however, it is not considered a nutritional claim the qualitative or quantitative indication of a nutrient, according to the legislation in force;"

The content of the definition is in essence the same as the one provided by Directive 90/496 on Nutrition Labelling.

We can notice a difference in terms of terminology between the English and the Portuguese, as the word 'claim' has been literally translated as 'declaration' (declaração nutricional**)**

2. Health Claims

Portuguese legislation does not contain any definition of health claims. The only definitions used are negative, i. e., they forbid medical claims and provide for a narrow interpretation of health claims. The Portuguese foodstuff labelling, presentation and advertising decree (Law Decree 170/92, see Annex 3) establishes some prohibitions related to health claims:

In its article 9, paragraph 1, point c) and d) it is stated that:

"1— [...] it is prohibited in advertisements to include any statement that might mislead the consumers, namely:

[...]
c) those that include medical, paramedical and pharmaceutical recommendations, or recommendations made by competent authorities or organisms in the nutritional field or public health, with the exception of those authorised by law;

d) those that make reference to members of medical, paramedical and pharmaceutical professions and, as well, to medical instruments or to the human body for illustrating physiological functions, even if stylised, with the exception of those that support the statements mentioned in the previous number authorised by law;"

Paragraph 2 of the same article adds the following:

"2— Without prejudice of the dispositions applicable to dietetic products and to mineral and table waters, it is prohibited in labelling to include any statements referring to the prevention or elimination of sickness."

The Portuguese foodstuff labelling, presentation and advertising decree limits itself to comply with the EU labelling Directive 79/112, in that it does not allow to claim that a foodstuff has the property of preventing, treating, or curing a human disease.

Compared with the Codex Alimentarius definitions as mentioned in the latest draft recommendations on health claims, Portuguese legislation does not allow disease risk reduction claims. The use of enhanced function claims seems to be limited.

3. Ethical Claims

Portuguese legislation does not contain any definition of ethical claims.

B. LEGISLATION IN PLACE

1. Nutritional Claims

Directive 90/496 on Nutrition Labelling has been implemented by Decree No. 751/93 from 23 August 1993 (see Annex 1).

Directive 89/398 on Foodstuffs for Particular Nutritional Uses has been implemented by a number of Law Decrees, which have been codified by Law Decree 227/99 of 22 June 1999 (see Annex 2).

2. Health Claims

Directive 79/112 on Labelling of Foodstuffs has been implemented by different Law Decrees, which have been codified by Law Decree 170/92 from 8 August 1992.

Directive 84/450 on Misleading Advertising has been implemented by Law Decree 330/90 of 23 October 1990 (there have been made several amendments to this Law Decree, the latest one in 1998 to include comparative advertising. A codified version is annexed to Law Decree No. 275/98 of 9 September 1998, see Annex 4).

3. Ethical Claims

There exists no specific legislation on ethical claims.

C. EXISTING PROHIBITIONS, RESTRICTIONS AND EXEMPTIONS

1. Nutritional Claims

a. Prohibitions/ Restrictions

Under article 2 of the Portuguese nutrition labelling decree (Decree 751/93, see Annex 1), nutritional claims may only refer to the energy value and to the following

nutrients: protein, carbohydrate, fat, fibre and sodium; as well as substances, which are part of or belong to one of the categories of these nutrients.

Vitamin and mineral claims are restricted to the following nutrients:

Nutrients	Recommended Daily Allowances (mg)	**Nutrients**	Recommended Daily Allowances (mg)
Vitamin A	800	Vitamin B12	1
Vitamin D	5	Biotin	0,15
VitaminE	10	Pantothenic acid	6
VitaminC	60	Calcium	800
Titamin	1,4	Phosphor	800
Riboflavina	1,6	Iron	14
Niacin	18	Magnesium	300
Vitamin B6	2	Zinc	15
Folic acid	200	Iodine	150

Such claims can only be made if these nutrients are contained to a significant amount in the foodstuff (15% of the RDA).

b. Exemptions

Article 1, paragraph 4, of the Portuguese nutrition labelling decree (Decree 751/93, see Annex 1), exempts natural mineral waters, as well as the other waters for human consumption, and diet integrators/ food supplements from its scope.

2. Health Claims

a. Prohibitions/ Restrictions

The Portuguese foodstuff labelling, presentation and advertising decree (Law Decree 170/92, see Annex 3) prohibits the use of health claims (see chapter A) 2).

The Advertising Code forbids certain advertising for alcoholic beverages, i.e. such advertising shall not suggest success, certain therapeutical properties or stimulating effects (article 17 of Advertising Code, see Annex 4).

b. Exemptions

The Portuguese foodstuff labelling, presentation and advertising decree (Law Decree 170/92, see Annex 3), also refers an exception concerning dietetic products, mineral and table waters (article 9, paragraph 2):

"Without prejudice of the dispositions applicable to dietetic products and to mineral and table waters, it is prohibited in labelling to include any statements referring to the prevention or elimination of sickness."

Nevertheless, the Portuguese Law Decree on dietetic products (Law Decree 227/99, see Annex 2) states that reference to the prevention, cure or treatment of diseases for these products is not allowed (Article 9 (1) e)).

3. Ethical Claims

There is no specific legislation for ethical claims under Portuguese Law. Nevertheless, the Advertising Code's (see Law Decree 275/98, Annex 4) prohibition of misleading advertising (article 11) applies, which is nearly a literal translation of the EU Misleading Advertising Directive 84/450 (article 2 and 3).

D. POLICY DEVELOPMENTS AND STAKEHOLDERS' POSITIONS

1. Nutritional Claims

Portuguese authorities consider the current legislation on nutritional claims satisfactory. Policy thinking is currently not focusing on nutritional claims. It is in any case considered to be subject to EU harmonisation policy.

One of the problems that was pointed out by the main Portuguese consumer association in terms of nutritional claims was the fact that nutritional labelling was only compulsory when a nutritional claim was made (see Portuguese Decree 751/93 on nutrition labelling, article 3, see Annex 1). In the consumer association's view, nutrition labelling should always be compulsory.

2. Health Claims

Portuguese authorities indicated that they had so far not reflected on the issue of health claims. No policy initiatives are currently planned. Nevertheless, food industry has had first contact with the Ministry of Agriculture and the Ministry of Health on a possible industry code of conduct on health claims (see below III.).

The competent authorities, and the Ministry of Health, consider that there are no significant barriers to trade with regard to health claims. Directive 79/112 is fully in force.

The consumer associations mentioned that there are relatively few identified cases of barriers to trade or lack of consumer protection but, according to them, this can be partly attributed to the lack of means on behalf of the consumer associations to inspect products being marketed or crossing borders.

The Portuguese food industry association considers that the Portuguese food industry is being disadvantaged, as the Portuguese authorities are on the one hand very restrictive in their practice vis-à-vis health claims, but on the other hand they allow the import of far-reaching health claims from other Member States. The association mentioned as an example the Omega 3 cholesterol claims made on some milk products.

3. Ethical Claims

In recent years a debate has emerged on this issue. In 1998, the General Union of Consumers ("União Geral de Consumidores" — UGC), promoted with the support of the Institute of Consumption ("Instituto do Consumo"), an information campaign aiming to raise awareness, and increase the consumption of, goods produced in conditions that were not socially degrading or in violation of the human rights. The campaign has stressed the need for the creation of a "social labelling" as a guarantee that the goods were produced in countries that respect the working conditions of their workers and the human rights.

There is no specific legislation on ethical claims in Portugal. Despite this legal vacuum, the national authorities, food industry and consumer associations contacted indicated that they were not aware of any problems in this area.

III. VOLUNTARY INSTRUMENTS AND OTHER PRACTICES

We found no voluntary instruments in place or other practices used in Portugal for either type of claims.

The Portuguese food industry association is currently working on a code of practice on health claims. This code will be an industry code and is aimed at putting Portuguese food industry on an equal footing with foreign producers importing products with health claims that Portuguese authorities do not allow. The aim is to get such a future code approved by the authorities.

The food industry association had so far a quite positive response from the Ministry of Agriculture. Discussions are currently on-going with the Ministry of Health. The food industry association considers that it will be a medium to long term project to get such a code of practice in place.

IV. VERIFICATION SYSTEMS

A. CRITERIA FOR SUBSTANTIATING CLAIMS

1. Nutritional Claims

The Portuguese nutrition labelling decree (Decree 751/93, see Annex 1) establishes the criteria that shall be respected in order to substantiate a nutritional claim in terms of energy value, vitamins, etc. It reproduces almost literally the Council Directive 90/496 of 24 September on the nutrition labelling of foodstuffs.

As it is stated in the results from the Commission Food Inspection Team (see Results of the Official Foodstuffs Control System in Portugal by the European Commission Foodstuffs Assessment Team, 10-14 March 1997), the legal basis for the official control of foodstuffs is very broad and complex. There is so far no specific transposition of the EU Food Control Directives 89/397/EEC and 93/99/EEC. The Portuguese authorities (*Direcção Geral da Fiscalização e Controlo da Qualidade Alimentar*) considered that the content of these Directives was already included in

existing Portuguese legislation. In any case, a draft law is currently being finalised for the transposition of these Directives.

Under the Portuguese decree on foodstuffs for particular nutritional uses (Law Decree 227/99, see Annex 2) the normal notification procedure for dietary foods as set out under Directive 89/398 on foods for particular nutritional foods applies. Article 7 of the decree defines the criteria for substantiating a claim.

According to paragraph 2, for the first commercialisation of a product the producer or the importer must submit to the Directorate General for Health (*Direcção-Geral de Saúde DGS*) an example of the respective label. DGS decides whether the product conforms with the criteria of a dietary food (which are set out in paragraph 2 points a) and b) of article 2.) If the product has already been commercialised in another Member State the producer or the importer must submit to DGS the indication of the entity to which the first notification of the label of the product was sent.

Whenever judged necessary, DGS is entitled, within a delay of 90 days from the reception of the label of a product, to demand a producer or importer for the submission of scientific work and all the data which shows the compliance of the product with the criteria established by the decree on foodstuffs for particular nutritional uses.

2. Health Claims

Health claims are not allowed in Portugal.

According to the consumer associations, the existing Portuguese legislation on health claims (see II) A) 2)) does not offer sufficient legal protection to consumers. The absence of clearly defined rules for substantiating claims implies that only if a striking threat to the health of consumers is identified by any of the legal persons entitled to take legal action there can be an investigation to determine if the claim is in violation of the law. This slow process combined with the lack of means of the consumers associations constitutes in their view an inefficient system for the protection of consumers rights.

The food industry association is against any pre-clearance systems, as already today only foodstuffs that are safe are allowed to be put on the market. It agrees that manufacturers should have available scientific documentation to prove that the claims made are scientifically justified.

3. Ethical Claims

There is no verification system for ethical claims.

There is no system or mechanism for the control, regulation or supervision of ethical claims. Consumer associations (e.g. Associação Portuguesa para a Defesa do Consumidor - DECO) are pressing for the introduction of mechanisms that could supervise the introduction of ethical claims. These mechanisms could have a legal nature or assume the form of voluntary instruments or codes of conduct to be agreed

between the consumer associations and the commercial associations or the organisations representing the different branches of products.

A proposal has been put forward by DECO which would consist of the introduction of a social label. No feedback has been registered from the authorities on this subject matter.

B. LEGAL/ADMINISTRATIVE SYSTEMS FOR VERIFYING CLAIMS

In Portugal the verification/inspection of labels is undertaken by an administrative system. The competencies of the different administrative authorities mentioned below sometimes overlap:

1) In accordance with Decree 98/97 (see Annex 6), the system in place for verifying claims is an ex-post system under the responsibility of the Directorate General for Surveillance and Control of Food Quality (*Direcção Geral de Fiscalização e Controlo da Qualidade Alimentar* - DGFCQA), which is attached to the Ministry of Agriculture. According to article 2 of the Decree 98/97 on the DGFCQA, this official body is entitled to verify, in co-ordination with the regional services from the Ministry of Agriculture, Regional Development and Fisheries, and without prejudice of the competencies of other authorities, the compliance of foodstuff labelling with Portuguese law.

   The DGFCQA is also required to prevent infractions against the quality, authenticity, composition, labelling of foodstuffs, food additives, and other substances.

   Furthermore, it is competent for the co-ordination and control, as well as the implementation of the regulations, on the production, preparation, packaging, labelling, transportation and sale of foodstuffs, ingredients and food additives. It is also in charge of the regulations for the packaging and other products that come in contact with foodstuffs (see Law Decree No. 98/97, article 12, see Annex 6).

2) The General Inspectorate of Economic Activities (*Inspecção Geral das Actividades Económicas* - IGAE) is the central service from the Ministry of Commerce that supervises the compliance of laws, regulations instructions, orders and other norms that regulate the economic activities. IGAE is competent for the investigation and instruction of the processes for administrative offences in respect of the law.

3) The Consumer Institute (*Instituto do Consumidor)* is a public institution in charge of the promotion of policies for the safeguard of consumers rights. It is responsible as well for the co-ordination and execution of the measures aiming at the protection, information and education of consumers, and for the support to consumer associations (Law No. 24/96 on Consumer Protection, see Annex 5). It is notably in charge of supervising the application of the Advertising Code (see Codified Advertising Code, article 38, see Annex 4).

C. LEGAL PERSON ENTITLED TO TAKE LEGAL ACTION

Under Portuguese Laws on Consumer Protection, the individual, consumer associations, public prosecution services and the Consumer Institute can start a judicial proceeding aiming at preventing, correcting or terminating any practice that damages the rights of consumers. This is namely practices that constitute a threat to health and physical integrity; practices consisting of generally forbidden clauses and commercial practices which are in violation of the law (Law No. 24/96, article 10 and article 13, see Annex 5.)

D. BURDEN OF PROOF

The burden of proof lies with the complainant. Nevertheless, the situation is different when the authorities start an investigation. The Advertising Code states that affirmations on the origin, nature, composition, properties and conditions of purchase of advertised goods and services have to be true and these affirmations must be able to be proven at all moment before the competent authorities (Advertising Code, article 10, see Annex 4).

E. APPLICATION OF PENALTIES

Penalties for misleading advertising range between $350,000 (1750 Euro) and $9000,000 (45000 Euro) under the Advertising Code (article 34, see Annex 4). The exact amount is decided by a Penalty Commission set up under the Advertising Code. In case of misleading advertising or advertising dangerous to health or consumer safety, the Consumer Institute can order the cessation or suspension of the advertisement. This decision is subject to judicial review.

Infractions of the law decree on foodstuffs for particular nutritional uses (article 9, see annex 2) can be fined with a maximum pecuniary penalty of $3.000.000 (15.000 euro). In addition, the authorities can confiscate the products in question, as well as suspend the marketing and sale of the products.

V. CASE LAW

1. Nutritional Claims

We did not come across any case law on nutritional claims.

2. Health Claims

There exists very little case law in Portugal on health claims. The case below was not decided in front of a civil court, but was analysed by the Directorate General for Health. The fine was determined by the Penalty Commission, established under the Advertising Code.

As a result of an inspection by the General Inspectorate of Economic Activities (IGAE), a complaint was put forward against a producer for marketing 41 packages of wheat bran cereals with a label containing, apart from indications on the ingredients

of the product, statements referring to the prevention or elimination of sickness properties of wheat bran.

The statements were the following:

> *"For a healthy life.*
> *It has been proved that regular fibre consumption helps to prevent some diseases that are characteristic of our time, like colon (large intestine) cancer, arteriosclerosis, obstipation, obesity or cardiovascular diseases".*

The product clearly claims to contain some properties that can help in the prevention of diseases like colon (large intestine) cancer, arteriosclerosis, obstipation, obesity or cardiovascular diseases which goes against the Portuguese foodstuff labelling, presentation and advertising decree (Law Decree 170/92, see Annex 3), in particular it violates its article 9, paragraph 2.

The Portuguese foodstuff labelling, presentation and advertising decree establishes an exception for dietetic products, mineral and table waters. The competent authority to analyse foodstuffs for particular nutritional uses is under Portuguese Law Decree 227/99 on dietetic products the Directorate General for Health (*Direcção Geral de Saúde* - UGS).

The DGS concluded that the advertising used on the packages of this product is prohibited and potentially it could mislead the consumer. Therefore, it has been classified as misleading advertising according to article 11, paragraph 1, of the Advertising Code by the Penalty Commission established under the Portuguese Advertising Code (see Annex 4).

The disrespect of the above mentioned legal dispositions is punishable by law according to article 34 of the Portuguese Advertising Code with a financial penalty between $350.000 (1750 Euro) and $9.000.000 (45000 Euro).

It was decided to apply the penalty of $1.5000.000 (7500 Euro) to the importer and distributor of the product and a penalty of $1.000.000 (5000 Euro) to the store where the product was for sale.

(Reference: *Comissão de Aplicação de Coimas em Matéria de Publicidade*, Proc. Nº 81-D, 10 de Julho de 1996)

3. Ethical Claims

We did not come across any case law on ethical claims.

VI. MEANS OF COMMUNICATION

There are no differences between the different means of communication with regard to claims or advertising.

VIII. STATISTICS ON CLAIMS

The authorities consulted and the consumer associations do not have any relevant statistics on claims. Only the *Associação Portuguesa para a Defesa do Consumidor* (DECO) indicated the following statistic on labelling where the association was invited to mediate in 1998 and 1999:

Complaints 1998	Nr. of complaints
Nutritional labelling	90
Health related labelling	96
Ethical labelling	14

Complaints 1999	Nr. of complaints
Nutritional labelling	92
Health related labelling	74
Ethical labelling	27

For most of the cases the problem was related with the fact that the labelling was written in other languages than Portuguese. A smaller number of complaints relate to the omission or incorrect use of information. Most of the cases are still under investigation by the competent authorities (*Direcção Geral de Fiscalização e Controlo da Qualidade Alimentar, Inspecção Geral das Actividades Económicas* and *Direcção Geral de Saúde*).

IX. ANNEXES

1. Portaria nº 751/93 from 23 August — Estabelece as condições a que deve obedecer a rotulagem nutricional dos géneros alimentícios em natureza, sejam ou não pré-embalados, a partir do momento em que se encontram no estado em que irão ser fornecidos ao consumidor final, bem como as regras relativas à sua apresentação.
2. Decreto-Lei nº 227/99 from 22 de June — Regula o regime jurídico aplicável aos géneros alimentícios destinados a uma alimentação especial.
3. Decreto-Lei nº 170/92 from 8 August — Estabelece os princípios e regras gerais a que deve obedecer a rotulagem, apresentação e publicidade dos géneros alimentícios.
4. Decreto-Lei nº 275/98 from 9 September — Altera o Código da Publicidade (with annex containing codified Advertising Code).
5. Lei nº 24/96 de 31 de Julho — Estabelece o regime legal aplicável à defesa dos Consumidores.
6. Decreto-Lei n.o 98/97 de 28 de Abril - Direcção Geral de Fiscalização e Controlo da Qualidade Alimentar.

X. DATABASE OF CONTACTS

N. SPAIN

I. EXECUTIVE ANALYSIS

A INTRODUCTION

This study aims to analyse the status of nutritional, health and ethical claims in Spain. Whilst much has been written about the first type of claim, both in legislative and in judicial terms, health claims have become more noticeable in the past five years with the increase in "border line products"(medicine or foodstuff). Ethical claim, on the other hand, are not perceived as an issue/problem, although in the last few months the public and 'civil society' at large have started to pay attention.

B. MEMBER STATE POLICY

1. Nutritional Claims

The definition of nutritional claim transposes Directive 90/496/CEE: the definition of "nutrition labelling" and "nutrition claim" are the same and related to energy provision, and to the same nutrient components of the food as in the Directive. Currently, the Spanish Government does not seem to wish to make any changes in its approach to this issue.

The Spanish Government has no plans to modify existing legislation, but is open to discussing the possibility of extending the list of allowable claims in the event of new nutrients.

2. Health Claims

There is no legal definition of health claims. A Royal Decree on the labelling of foodstuffs transposes Directive 79/112/EEC prohibiting claims that attribute disease prevention, therapeutic or curative properties to a foodstuff. Thus, if a claim includes a comparison with a medication, the relevant pharmaceutical legislation will apply.

However, a voluntary agreement (see below) providing manufacturers with guidelines provide a definition as:

- any claim, which makes reference to the effects of one or several of the nutrients or ingredients of a foodstuffs on the human body;
- any claim, which makes reference to a foodstuff's effect on health; and/or
- any claim, which refers to healthy eating habits.

The Federation of Food and Drink Industry (FIAB), together with the Ministry of Health, initiated a Voluntary Agreement. This agreement provides for certain health claims if they meet some specific requirements.

The authorities are somewhat skeptical about health claims as they could mislead the consumer and even if they are presented as a way of increasing consumer information

and well-being, they may actually serve other interests. Consequently, a health claim becomes a marketing tool. One solution to the problem of health claims would be to draw-up a positive list of claims, providing clear-cut conditions of use.

3. Ethical claims

There is no specific legislation regulating claims, nor is there any legal definition and nor is there any real interest on them from the point of view of the Public Authorities.

C. VOLUNTARY INSTRUMENT

Im March 1998, FIAB (Federation of Beverage and Agro-Food Industry) together with the Ministry of Health agreed a voluntary agreement to be applied to the publicity of health related foodstuff properties, whilst still in accordance to the Spanish implementing measures of 79.112.

As well as a clear definition (see above), a positive list of forbidden claims is given, drawn-up on the basis of the claim contents, and also on the grounds of the way they have been formulated (the text states: "the value each word has"). A number of conditions to be fulfilled by the claim are given, for example: the claim should be backed by scientific proof; the nutrient has to be present in "significant quantities"; the claim also has to be followed by a statement on the importance of a balanced diet, etc. A follow-up Committee has been set-up to respond to complaints.

The voluntary agreement follows very much the spirit of latest draft Codex guidelines.

Until now no voluntary agreement has been reached in the field of ethical claims. On the industry side, many Codes of conduct exist. They reflect their commitment to the respect for different types of norms or requirements. Consumer organisations try to bring the issue to the surface and various initiatives have been begun including the creation of list of "guilty enterprises" and the stamping of products with ethical labels.

D. VERIFICATION SYSTEMS

Individual consumers, association of consumers or individual companies can take legal action against a claim either by following the guidelines of the General Law on advertising, which transposes Directive 84/450/CEE, or by using the Law on the protection of Consumers and Users and the Royal decree on Infractions and Sanctions in the areas of Consumer Protection and the Agro-food industry.

There are no pre-guidelines for accepting claims. Usually this process takes place at the regional level. At a federal level, however, a case can be brought before the *Intituto Nacional de Consumo* (National Institute of Consumption). This autonomous body, dependent on the Health and Consumption Ministry, has received the mission of investigating claims and the powers to ban a claim or even a product. Its decision can then be taken before the Supreme Court.

E. MEANS OF COMMUNICATION

There are no differences between the different means of communication with regard to claims or advertising.

F. BARRIERS TO TRADE

Nothing has been noted as acting as a barrier to trade.

G. CASE LAW

There is no body of case law relevant to claims, except for one single court case, which ruled in favour of a health claim.

I. STAKEHOLDERS ANALYSIS

1. Government Authorities

- Government Authorities are satisfied with current national legislation and no particular problem has been highlighted regarding nutritional claims. On health claims, the problems arising with this new category of claims are well known, although there is some hesitation to see further European Union intervention.

2 Consumer Organisations

- Consumers would welcome EU action on health claims and regret the fact that ethical claims are not in any way taken into account in Spanish or European legislation per se.

3. Industry

- FIAB is currently supporting CIAA's initiatives towards their being European legislation on the harmonisation of health claims. Industry Associations clearly and strongly advocate in favour of EU harmonisation on health claims. It has been a growing market for several years now, and, in order to avoid barriers to trade, both internally and at the European level, such a measure, in combination with the Codex work, would constitute real progress.

II. MEMBER STATE POLICY

A. DEFINITIONS OF CLAIMS

1. Nutritional Claims

Nutritional claims are defined as all labels or advertising which, confirm, suggest, or imply that a foodstuff possesses specific nutritional properties. The properties can only refer to:

- the foodstuff's energy value (reduced, increased or eliminated); or
- the actual nutrients present in the foodstuff (reduced, increased or eliminated).

The claim cannot make reference to the effect or lack of effect, properties or actions, that these nutrients may have.

Example of a nutrient claim: "High in fibre content"

Vitamin content may be shown in chart format.

This definition is included in Royal Decree 930/1992[24], which transposes Directive 90/496/CEE.

An agreement reached by the Inter-ministerial Committee on the Regulation of Foodstuffs, stipulates that the use of the word "light" is allowed only if the product has undergone treatment reducing its energy content by 30%.

2. Health Claims

A legal definition for health claims does not exist. If a claim includes a comparison with a medication, then it is the pharmaceutical product.

Several legislative pieces do, however, list those claims that are permitted or prohibited, distinguishing between claims related to foodstuffs and claims related to other products and services.

Hence, regarding claims related to foodstuffs, Royal Decree 212/92[25] on the labelling of foodstuffs transposes Directive 79/112/EEC and stipulates that a claim cannot attribute disease prevention, therapeutic or curative properties to the foodstuff. In addition, Royal Decree 1907/1996[26] lists which health claims related to foodstuffs are prohibited (*please see section on prohibitions and restrictions).*

[24] See Annex 1.*Real Decreto 930/1992*, 17.07.1992, BOE 187.
[25] See Annex 6. *Real Decreto 212/1992*, 06.03.1992, BOE 72.
[26] See Annex 5. *Real Decreto 1907/1996*, 02.08.1996, BOE 189.

In order to clarify the scope of these prohibitions, a definition for health claims was developed under the Voluntary Agreement[27] signed between the "*Ministerio de Salud y de Consumo*" (Ministry of Health and Consumer Affairs) and the "*Federacion Espanola de Industrias de Alimentacion y Bebidas*" (Federation of Beverage and Agro-Food Industries (FIAB)) on 20 March 1998 (*see section on voluntary agreements).*

Health Claims are defined in this Voluntary Agreement as:

- any claim, which makes reference to the effects of one or several of the nutrients or ingredients of a foodstuffs on the human body;
- any claim, which makes reference to a foodstuff's effect on health; and/or
- any claim, which refers to healthy eating habits.

Regarding products and services other than foodstuffs, Royal Decree 1907/1996[28] regulates the advertising and commercial promotion of health related products, activities or services, by stipulating which claims are permitted and which are not. A list of the claims, which are prohibited under this Directive, is included in section D on Prohibitions, Restrictions and Exemptions.

3. Ethical Claims

There is no definition for Ethical Claims.

B. LEGISLATION IN PLACE

1. Nutritional Claims

Royal Decree 212/1992[29] approves the "General Norm on Claims, presentation and publicity of foodstuffs", which was approved by the Royal Decree 1122/7988, as a consequence of the necessary transposition of Directive 79/112/CEE. The key points are:

- Area of Application: all foodstuffs' claims, labelling, presentation and publicity
- Prohibitions: of misleading the consumer on the product's characteristics (nature, identity, qualities, composition, quantity, origin, means of fabrication); of attributing effects that the foodstuff does not possess.
- The fifth chapter details the obligatory information to be given (nature, ingredients, quantities, date of expiry, specific storage,) and the way to present the obligatory information.

Royal Decree 930/1992[30] on the Nutrition Labelling of Foodstuffs gives a definition for legal nutritional claims and sets down the information, which nutritional claims must contain.

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[27] See Annex 9. Ministerio de Sanidad y de Consumo/Federacion de Industriales de la Alimentacion y bebidas : *Acuerdo interpretativo sobre la publicidad de las propiedades d elos alimentos en relacion con la salud.*
[28] See Annex 5. *Op.cit*
[29] See Annex 6. *Op.cit*.
[30] See Annex 1. *Op.cit*

Laws 34/1988, 26/84[31] and Royal Decree 1945/1983[32] sets down the legal framework in the event of false or misleading claims.

Law 26/84 for the Consumers and Users defence defines their basic rights:

- to be protected against any risk that could affect their Health and Safety;
- to be protected in their economic and social rights;
- to be compensated;
- to be given the correct information on different products or services as well as to be given education on these issues;
- to be represented (through associations, associations, groups, confederations); and
- to be judicially, administratively and technically protected.

The text is then divided into different sections: Health protection and security, economic and social interests protection, information rights, right to education and formation, representation, consultation and participation rights, guarantees and responsibilities infractions and sanctions.

Royal Decree 1945/1983 lists the different types of infractions (sanitary infraction, infractions in the field of consumer protection, infractions in the area of foodstuff quality). It then lists the different applicable sanctions and deals with the problem of investigations (see below).

Royal Decree 2685/1976[33] sets down the legal framework for the approval of Foodstuffs for Particular Nutritional Uses(*diet or /and specific foodstuffs*).

Royal Decree 1809/1991[34] regulates the marketing of these foodstuffs and transposes Directive 89/398/CEE into national legislation. The labelling of these foodstuffs is regulated by Royal Decree 1809/1991[35].

2. Health Claims

Spanish legislation was strict in the way that it used to consider claims related to health. Finding itself in a very difficult situation (with the number of "middle-way products" – between foodstuff and medicines- increasing every year), the Spanish food industry asked the Ministry of Health for a more appropriate way of dealing with this issue, which led to a Voluntary Agreement.

Until 1996, Royal Decree 212/92[36] was the only legislative framework, which regulated the use of health claims that do not fall under pharmaceutical legislation. (Chapter III, article 4.1.4 states that claims could neither attribute to any foodstuff the property of preventing, treating, or curing a human disease, nor mention these properties.).

[31] See Annex 8. *Law 26/1984* for the Consumers and Users defence.
[32] See Annex 7. *Real Decreto 1945/1983*, 22. 06. 1983, BOE 72.
[33] See Annex 2. *Real Decreto 2685/1976*, 16. 10. 1976, BOE 1984.
[34] See Annex 3. *Real Decreto 1809/1991,* 13.12.1991, BOE 308.
[35] See Annex 3. *Ibid.*
[36] See Annex 6., *op.cit.*

However, the Spanish authorities started to examine the question of health claims more closely as early as 1995, with the proliferation of so-called "miracle products", which included non-food goods such as: weight loss apparatus, wristbands, etc. This new kind of product between a foodstuff and a medicine was being developed and needed appropriate tools, which led to the adoption of the Royal Decree 1907/96[37] "on publicity and commercial promotion of products, activities, or services with an alleged sanitary aim". The decree is relevant for the area of foodstuffs in its Article 4 as it prohibits in certain listed cases, any kind of publicity or promotion on products, materials, substances, energies or methods **if** the products, materials, substances, energies or methods are said to possesses a sanitary aim.

This decree has also had an impact on the food industry (*see II. A.2)* and the Ministry of Health and Consumer Affairs later used it as a vehicle against companies, which used such prohibited health claims.

This evolution prompted the food industry, through FIAB (the Federation of Agro-Food Industries), to seek a Voluntary Agreement[38] with the Ministry of Health and Consumption, on the use of health claims on food products *(please see section III on Voluntary Instruments).*

N.B : Natural mineral waters and special diet foodstuffs fall under their own specific legislation.

3. Ethical Claims

There is no legislation regulating the use of Ethical Claims.

C. EXISTING PROHIBITIONS, RESTRICTIONS AND EXEMPTIONS

1. Nutritional Claims

Nutritional claims that do not meet the requirements and stipulations of national legislation on the use of such claims are prohibited.

Strict restrictions of the contents of the claim and on the composition of the foodstuff, are set in the legislation.

Exemptions are allowed only after careful analysis by the competent authorities, which include:

- The Ministry of Health and Consumer Affairs;
- Ministry of Agriculture;
- Ministry of Economy;
- Regional equivalents of the three ministries mentioned above.

[37] See Annex 5., *op.cit*
[38] See Annex 9., *op.cit.*

The definitions and prohibitions established under Royal Decree 212/1992[39] are in line with those set out in Directive 79/112/CEE. As such they do not represent a barrier to trade in foodstuffs.

2. Health Claims

The prohibitions applied in Spain correspond to the rules set out in Article 2 of Directive 79/112/CEE and transposed by Royal Decree 212/1992[40]. These rules prohibit any claim which "attributes disease prevention or curative properties to the foodstuff". In addition, Royal Decree 1907/1996[41] specifically lists those claims, which are not allowed under Spanish legislation, namely claims:

- which attribute prevention, therapeutic or curative properties for transmissible diseases, cancers, insomnia, diabetes, and other metabolic illnesses;
- which refer to weight loss properties or against obesity;
- which attribute therapeutic properties against diseases to the product/service, without complying with pharmaceutical and medical rules and regulations;
- which guarantee the product/service will provide a cure or relief;
- which use any type of authorisation, recognition or approval from health authorities from other countries;
- which refer to its use in sanitary centres or to its distribution in pharmacies.
- which use testimony of health professionals, famous people or of real or supposed patients, to increase consumption of the good;
- which aim to replace standard and common nutritional habits, especially when related to maternity, breast-feeding, childhood or old age;
- which attribute concrete and specific preventive, therapeutic, or curative properties to particular foodstuffs' form, presentation, or brand.
- which attribute to diet foodstuff preventive, therapeutic, curative or other properties, that are distinct from the usually known properties of these products;
- which attribute different properties to cosmetics, than those accepted under legislation regulating the cosmetics industry;
- which suggest or indicate that use or consumption of the product will improve physical, psychological, athletic or sexual activities;
- which use the word "natural" as a characteristic of the product which gives it therapeutic or preventive properties;
- which give the product a superfluous character or which claim it can replace medication or legally recognised health products;
- which give the product a superfluous character or which aim to replace the need for advice from health professionals;
- which, in general give the product prevention, therapeutic or curative properties, without the necessary support and verification from the appropriate authorities.

However, several **exemptions** to this rule are listed under the Voluntary Agreement signed between FIAB and the Ministry of Health and Consumer Affairs.

[39] See Annex 6., *op.cit*
[40] See Annex 6., *op.cit.*
[41] See Annex 5., *op.cit.*

3. Ethical Claims

Given the lack of legislation on the use of ethical claims and the lack of any such claims on the Spanish market, there are currently no rules prohibiting or restricting the use of such claims.

D. POLICY DEVELOPMENTS AND STAKEHOLDERS' POSITIONS

1. Nutritional Claims

The Spanish Government has no plans to modify existing legislation, but is open to discussing the possibility of extending the list of allowable claims in the event of new nutrients.

2. Health Claims

The Ministry of Health has highlighted a number of "problems" related to the identification and definition of authorised Health claims:

- It is difficult to make a clear distinction between the type of health claim - still to be defined - that could be authorised, and the claims that attribute to any foodstuff "the property of preventing, treating or curing human disease", and that are prohibited in Royal Decree 212/1992 (which transposes the provision set up under the article 2 of Directive 79/112/CEE).
- Added to this problem of definition is the problem of the criteria that could constitute grounds for such a definition: it would be difficult, for instance, to establish criteria in terms of percentage or threshold
- Finally, it is also difficult to draw a line between "physiologic effects" and "effects on Health".

From the point of view of the Ministries, making a health claim is questionable since they could mislead the consumer and even if they are presented as a way of increasing consumer information and well-being, they may actually serve other interests. Consequently, a health claim becomes a marketing tool. Moreover, the authorisation of such health claims cannot be considered as the best way of helping a consumer to take the right decisions regarding his or her health. One should also consider the fact that, given the rapid path of change in scientific knowledge, health claims (if they were authorised) would have to be constantly changed.

From the Ministry's point of view, one solution to the problem of health claims would be to draw-up a positive list of claims, providing clear-cut conditions of use. In such a sensitive area**,** should any other solution be chosen, it would be signify that a mercantile approach would have overcome public Health policy.

3. Ethical Claims

It is highly unlikely that the Government will begin to analyse the issue of ethical claims in the near future. However a domino effect from the current Consumer NGOs campaign to boycott products manufactured by children or by workers receiving subsidence salaries may speed up the process.

In fact, some consumer organisations have tried to make the public aware of this issue. Hence, the "*Organizacion de consumidores y Usarios*" (Consumers and Users Organisation) campaigns. Even if organisations and institutions have not yet received responsibilities in this area, this particular consumer organisation has tried to organise campaigns ("*ropa limpia*" i.e "clean clothes"), to provide information on how to identify the type of enterprises that produces supposedly "dirty" products (a list of these firms is made available to the consumer who wishes to know more about the issue), and to make the promotion of "*el comercio justo*" (i.e fair trade).

In its May 1999 issue[42], the OCU publication *Compra Maostra* dedicates an article to "*sellos de comercio justo*" (fair trade labels). It says that "one way to inform consists in attributing labels to the enterprises, which show that they respect human rights in the way they treat their employees. Among other conditions are a fair salary; labour contract; no children work, etc. In Spain only the so-called "fair trade" shops sell this kind of labelled products. In addition, these specialised shops also sell products that have been imported through recognised importers, known for their respect of workers' rights. In Spain, these importers include Alternativa 3, solidaridad International, Intermon and Equimercado e Ideas.

Moreover, the article mentions the possibility for the OCU to add to their traditional technical criteria for the analysis of products, some ethical criteria.

III. VOLUNTARY INSTRUMENTS USED

A. VOLUNTARY INSTRUMENTS IN PLACE

1. Nutritional Claims

Not applicable.

2. Health Claims

A Decree from the Minister of Health[43] was published on the 2 August 1996, banning any publicity of products (including food) related to health benefits. The FIAB (Federation of Beverage and Agro-Food Industry) asked the Minister of Health for an agreement to interpret it in a more flexible and appropriate way, taking Directive 79/112 EEC into account. After one and a half years of work, an agreement[44] was finally signed in March 1998.

This Voluntary Agreement will be applied to the Publicity of Health related foodstuff properties.

a. Existing strict prohibitions that will not be covered by the Voluntary Agreement

[42] OCU. *Compra Maostra*, n.225, Mayo 1999
[43] See Annex 5., *op.cit.*
[44] See Annex 9., op.cit

The existing legislation is recalled and, on this basis, strict exclusion from the Voluntary Agreement's area of application are highlighted: foodstuff claims attributing preventive, therapeutic or curative properties as stated in Real Decree 212/1992[45]; claims related to special foodstuff for diet (Real Decreto 2685/76[46]), special legislation established through technico-sanitary reglementation (Real Decreto 1809/91[47]; claims related to mineral water (Real Decreto 1164/91), nutritional claims already covered by Royal Decrees 930/1992, 2685/1976, 1809/1991, 1426/198[48].

b. **Guidelines for assessing authorised health claims**

Other claims might be allowed even it is said that "there are differences of interpretation on where to locate the frontier between this type of allowed claims and the strictly forbidden one."

In order to help in drawing this line, a positive list of forbidden claims is given. This list has been drawn up on the basis of the claim contents, and also on the grounds of the way they have been formulated (the text states: "the value each word has").

The document also gives some conditions that should be fulfilled by the claim. The claim should be backed by scientific proof showing that the information is true and accurate. The nutrient, which is said to possess virtues, has to be present in "significant quantities". The claim also has to be followed by a statement on the importance of a balanced diet.

These requirements are consistent with the "general principles for making Health claims", established in the *Codex Alimentarius* (1997). The *Codex Alimentarius* defines a health claim as "any representation that states, suggests or implies that a relationship exists between a food or nutrient or other substance contained in a food, and a disease or health related condition". The Spanish Voluntary Agreement gives a very similar definition: "any claim related to the function of a nutrient on the human body, on Health; or related to healthy food habits".

The parallel between the two texts can also be made by comparing the sections on "general principles for making Health Claims". The *Codex Alimentarius* lists the need for scientific evidence, states that substantiation should demonstrate efficacy with an appropriate amount of intake, that health claims should be justified in the context of the whole diet and must be applicable to the amount of food normally consumed.

The Voluntary Agreement states that a "health claim will need to be supported by scientific proof; the nutrient will have to be present in the foodstuff in an appropriate quantity; the claim will have to be followed by the mention of the importance of a balanced diet; and it will not be possible to suggest that a specific brand produces peculiar effects".

[45] See Annex 6., *op.cit*
[46] See Annex 2., *op.cit*
[47] See Annex 3., *op.cit.*
[48] See Annexes 1,2,3,4, *op.cit*

Moreover, because of the ambiguous nature of this type of claim, the Spanish Voluntary Agreement also establishes a **Follow-up Committee** (Comision de seguimiento) consisting of:

- The Director-General of the Ministry of Health and Consumer Affairs;
- The Sub-Director General for Hygiene and Foodstuffs, of the Ministry of Health and Consumer Affairs;
- The Secretary-General of FIAB and
- The Director of the Department on Foodstuffs Law, of FIAB.

Under a request from a third party (a consumer or industry representative), the Follow-up Committee will investigate whether a claim is allowed or not, under the rules of the agreement. The holder of the claim can present his arguments justifying the claim to the members of the Committee, if he so requests it. The Committee has **10 days** to give its verdict of the claim. If after this time, a conclusion by the Committee has not been reached, the claim is allowed.

The agreement will be regularly submitted to revision "aiming at adapting it to the experience the following-up committee will have acquired".

Since its creation, the Follow-up Committee has carried out 50 investigations into the acceptability of various claims.

3. Ethical Claims

There is no Voluntary Agreement on Ethical claims yet.

B. DEFINITIONS USED IN THE VOLUNTARY INSTRUMENTS

1. Nutritional Claims

Not applicable.

2. Health Claims

Under the Voluntary Agreement, Health Claims are defined as:

- any claim, which makes reference to the effects of one or several of the nutrients or ingredients of a foodstuffs on the human body;
- any claim, which makes reference to a foodstuffs effect on health; and/or
- any claim, which refers to healthy eating habits.

3. Ethical Claims

Not applicable.

C. EXISTING PROHIBITIONS, RESTRICTIONS AND EXEMPTIONS

1. Nutritional Claims

Not applicable

2. Health Claims

The following claims are not covered by the voluntary agreement.

- Claims, which give a foodstuff, disease prevention, therapeutic and curative properties;
- Claims, which refer to weight loss and/or special diets which are regulated under Royal Decree 2685/76[49], and the Technical-Health Regulations as laid out under Royal Decree 1809/91[50];
- Claims used by the bottled water industry;
- Nutritional Claims such as "contains vitamin A, or, with calcium", which are regulated under Royal Decree 930/92.

The voluntary agreement also establishes that the words used in health claim should not be categorical, given that physiological effects vary from person to person. However, words such as "facilitates", "favours", "help", etc, are allowed.

The voluntary agreement also includes a non-exhaustive list of claims, which are not allowed. Those words in the claims, which are prohibited, appear in bold.

- Regenerating effect or action;
- Invigorating effect or action;
- Relaxing effect or action;
- The routine consumption of X diminishes the risk of suffering from …;
- Avoids or substitutes the need for medical treatment;
- Favors your natural defences;
- Protects you from X disease;
- Helps avoid or substitutes the need for medicines;
- Helps protect you from intestinal infections;
- Cures constipation
- Helps you fight osteoporosis;
- Stimulates the immune system;
- Facilitates the elimination of cholesterol;
- Facilities proper bone ossification;
- Fibre prevents colon cancer;
- X oranges are recommended by the World Health Organisation;
- Product X helps you lose weight;
- Regular ingestion of product X is recommended in the fight against kidney gallstones.

Questions or doubts as regards the legality of a claim are analysed by the Follow-up Committee established under the Voluntary Agreement. The conclusions of the

[49] See Annex 2., *op.cit*
[50] See Annex 3., *op. cit*

Committee are not, however, legally binding and consumers can, at all times, use the judiciary system to clarify the legality of a claim.

IV. VERIFICATION SYSTEMS

A. CRITERIA FOR SUBSTANTIATING CLAIMS

1. Nutritional Claims

The legislation on nutritional claims (see part II) gives precise criteria for substantiating claims (nature, quantity, name of the ingredients used, source of the figures used, etc…).

2. Health Claims

As specified in Royal Decrees 212/1992 and 1907/1996[51].

The second additional disposition of the royal Decree 1907/1996 says that the General Direction of Public Health will produce certifications or reports on diet foodstuffs, foodstuffs and other products of human use or consumption having a sanitary aim.

It further states that the General Direction of Public Health, having taken into account the reports from the "Sanitary Technology Evaluation Agency" and other relevant reports, will be able to say if they constitute technical or scientific proof, recognized as such by the sanitary administration of the State, as a consequence of what has been established in article 4.16 (the Decree's key article: it prohibits foodstuffs claims attributing preventive or therapeutic effects that are not supported by enough technical or scientific proofs).

The Voluntary Agreement[52] also gives some criteria for substantiating this type of claim: a health claim will only be possible if there exists scientific proof, showing the truth and the accuracy of the objective elements given or suggested in the claim; the nutrient has to be present in significant quantity. However, as parts of a voluntary agreement, these criteria are not binding.

3. Ethical Claims

No criteria.

B. LEGAL/ADMINISTRATIVE SYSTEMS FOR VERIFYING CLAIMS

[51] See Annexes 6 and 5., *op. cit.*
[52] See Annex 9., *op. Cit.*

1. Pre-Clearance Rules/ Guidelines

There are no pre-guidelines for accepting claims, other than the owners' responsibility of ensuring that the rules established under the relevant nutritional and health claim legislation, are respected. The legality of claims is monitored at various points of the products life cycle:

- Manufacturing;
- Border controls;
- Warehouses and distribution;
- Retail and sales and
- Advertising.

2. Post-Clearance Rules/ Guidelines

These are established under the relevant legislative rules.

3. Civil or criminal law redress procedures

Individual consumers, consumer associations and individual companies can take legal action against a claim through either the regional courts or the federal Supreme Court.

To date, all cases have been brought to the regional courts. For example, it was the Tribunal of Biscaya, which ruled that the statement "Helps you to regulate the level of cholesterol" is allowed, on the basis that "cholesterol" is not a human illness.

As such it corresponds to the rules established under Royal Decree 212/92[53] and the Voluntary Agreement[54]between the Health Ministry and FIAB

At the federal level, a case is usually brought first before the *Instituto Nacional del Consumo* (National Institute of Consumption, see below), which has the power to:

- freeze the sales of a product until a decision has been taken, on the basis that the products presents a hazard to human health;
- ban the claim if a decision is taken that it is illegal; or
- ban the product based on a decision that it is dangerous to human health.

The **National Institute of Consumption** is an autonomous organisation, under the auspices of the Ministry of Health and Consumption. Under Law 26/84[55] for the Consumers and Users defence and article 51 of the Spanish Constitution, this institute's role is to promote the consumers' rights.

It is constituted by a president, a vice president, a general secretariat, and two subdivisions. The first subdivision is responsible for Education and Formation, consumers' information, and "arbitrage". The second one is responsible for technical assistance to the Consumption administrations, the administrative co-ordination and

[53] See Annex 6., *op.cit.*
[54] See Annex 9., *op. cit*
[55] See Annex8., *op.cit*

co-operation, the analysis of the Market and the follow-up of publicity. Part of this second subdivision comprises the **Investigation and Quality Control Center**. This Center undertakes analysis and tests on consumption products, aiming at verifying their security and commercial quality. These analysis are based on evidence coming from local Consumption Inspection Services, the National Institute for Consumption, Municipal Consumer Information Offices, Tribunals, and other official organisations.

Co-operation with other organisations takes place through the production of reports, diffusion of analytical methods, participation in committees and working groups. This co-operation is established with other control laboratories, Institutions (General administration, "Comunidades Autonomas", "Ayuntamientos"), normalisation organisms (CEN, ENAC…), and other organisations that have the responsibility for elaborating legal norms (CIOA).

The Institute's decision can then be taken before the Supreme Court.

There have been very few actual court cases regarding claims in Spain, except in the area of "miracle" product claims. This resulted in the adoption of 1907/96 banning all health claims except for those covered by the voluntary agreement with FIAB.

b. Specific procedures for claims

The procedures for both nutritional and health claims are those established under the relevant legislation for misleading advertising. Law 26/1984 states that infractions will be submitted to administrative sanctions and that that the cases will brought to *Tribunales de Justicias*. It then lists the different type of sanctions.

c. Out-of-court procedures

All health claims are allowed if they follow the guidelines set in the relevant legislation (Royal Decrees 212/92 and 1907/96[56]) and the rules established in the FIAB voluntary agreement. If doubts exist as to the legality of the claim, the Follow-up Committee can be requested to investigate whether it meets the rules set in the agreement, prior to the release of the claim. In such a case, the Committee has 10 working days to give its conclusions on the inquiry. The claim is cleared if a decision has not been taken by this deadline, and/or if the Committee approves the claim. During its investigation, the Follow-up Committee can temporarily ban the use of the claim until a decision has been taken. The owner of the claim has the right to request that he/she be allowed to present arguments in favor of the claim, during the investigation. To date the Follow-up Committee has studied more than 50 cases.

The Consumer Association, CECU, has also been involved in verifying claims, either at its own initiative or by request of individual consumers. In the case that CECU decides that a claim warrants investigation, it will first carry out its own investigation and then, if its decides sufficient cause for further action exists, it can present its findings to the Consumer Institute, requesting further investigation from the Government body.

[56] See Annexes 5 and 6., *op.cit*

C. LEGAL PERSONS ENTITLED TO TAKE LEGAL ACTION

Federal and regional health and consumer administrations as well as consumer associations, industry, and individual consumers are allowed to take legal action against claims, following the guidelines of Law 34/1988 on General Rules of Advertising (a distinction between advertising and claims does not exist within the Spanish legal framework). This law is a transposition of Directive 84/450/CEE. Consumers also have recourse to Law 26/1984 [57]on the Protection of Consumers and Users, and to Royal Decree 1945/1989 on Infractions and Sanctions in the areas of Consumer Protection and the agro-food industry.

Legal action can be taken to both the regional and federal courts, and to date most cases have been dealt with by the regional courts.

D. BURDEN OF PROOF

The burden of proof is on public authorities to show that an offence has occurred under the legislation.

Law 26/1984 states in its chapter "protection of economic and social interests" that "doubt in the interpretation will be solved against those who will have written them" and, further, that public authorities and the relevant administration bodies competent in consumption matters will adopt and promote adequate means in order to help the consumer(s), individually or collectively, that will find himself in situation of inferiority." Chapter 10 states that the State Administration will have to promote and develop the consumer's protection and defence.

Thus, legislation on nutritional claims and health claims indicate which particular administration is responsible in particular cases.

E. APPLICABLE PENALTIES

The penalties applied in the event a claim is proven not to comply with relevant legislation are:

- Fines (amount fixed by the court or Consumer Institute);
- Destruction of the merchandise; and
- Ban on the sale of the product.

V. CASE LAW

There is no body of case law in Spain. The only case law that we could find relate to the Tribunal of Biscaya (19.04.1995) in the "margarine FLORA" ruled that the statement "helps you to regulate the level of cholesterol" was allowed, on the basis that "cholesterol" was not a human illness, and, as such, corresponded to the rules established under the Royal Decree 212/1992, and the Voluntary Agreement.[58]

[57] See Annex 8., *op.cit*
[58] See Annexes 6 and 9, *op.cit*

VI. MEANS OF COMMUNICATION

For all types of claims, non-compliance with the specific legal requirements on claims (see part on legislation) is considered to be misleading publicity, defined by the Law 34/1.988 as the publicity that "in any way, even through the presentation, induce or may induce an error, influence the economic behavior, or jeopardize a competitor's position"

Spain introduced a self regulatory body for the media.

The Association for Advertising Self Regulation (APP) is the only organisation in Spain dealing with self-regulation in advertising. It is composed of the following members: 73 advertisers, 22 agencies, 14 representatives of the media and 6 industry organisations (the Spanish Advertiser's association, the Spanish Proprietary Products Association, the Spanish Advertising Agencies'Association, the Advertising Media of Spain Association, the Spanish Outdoor Advertising Association, and the Federation of regional Radio and Television Organisations).

It is a private, non-profit making body, independent from the government. It is composed of a Board of Directors, and a Director General who together form the governing body, a Secretariat, and a Jury (made up of 4 legal experts and 6 representatives of business and advertising associations, presided over by a senior academic and an administrative law specialist).

It aims at ensuring compliance with the legal and self regulatory provisions, which regulate advertising as a form of commercial communication, and to regulate both the form and content of advertising in all media. To this end, it considers and resolves cases of non-compliance, provides pre-publication advice and drafts guidelines for legal and ethical advertising practices.

The Codes:
- Code of Advertising Practice (December 1996)
- Sector specifics: such as the "rules for the advertising of food products"(1985).

The AAP provides copy advice on campaigns, examines advertising for compliance with its code, handle complaints, etc.

A number of sanctions can be proposed (to ask the advertiser to withdraw or modify the advertisement, to request the media to cease publication of the advertisement, to publish the adjudication in the APP's monthly newsletter, which is sent to members and the media, to expel the advertiser or advertising agency from membership).

VII. STATISTICS ON CLAIMS

There is no information relating to statistics.

VIII. ANNEXES

Legislation

1) Real Decreto 930/1992, 17.07.1992 (on nutritional claims), BOE 187.
2) Real Decreto 2685/1976, 16.10.1976 (on technico-sanitary reglementation for theelaboration, circulation and trade of diet foodstuffs), BOE 284.
3) Real Decreto 1809/1991, 13.12.1991, (modification of the technico-sanitary reglementation. On the elaboration, circulation and trade of diet foodstuffs), BOE 308.
4) Real Decreto 1426/1988, 25.11.1988, BOE 288
5) Real decreto 1907/1998, 02.08.1996, on publicity and commercial promotion on products activities or services having a sanitary aim, BOE 189
6) Real Decreto 212/1992, 06.03.1992 (General norm on foodstuff claims, presentation and publicity), BOE 72
7) Real Decreto 1945/1983, 22.06.1983 on infraction and sanctions regarding the consumer and the agro-alimentarian defence. BOE 168
8) Law 26/1984, 19.06.1984 for the Consumers and Users defence, BOE 176.

Other Documents

9) Ministerio de Sanidad y de Consumo / Federacion espanola de Industriales de Alimentacion y Bebidas :
Acuerdo interpretativo sobre la publicidad de las propiedades de los alimentos en relacion con la salud.
10) El Instituo Nacional de Consumo http://www.consumo-inc.es/presentainc.htm
11) EASA: The blue Book, *Advertising and self-regulation*
12) OCU Compra Maostra, no.225, May 1999.

IX. DATABASE OF CONTACTS

O. SWEDEN

I. EXECUTIVE ANALYSIS

A. INTRODUCTION

This study on nutritional, health and ethical claims has been well received by all interested parties/stakeholders who together have been very co-operative in meeting and providing information.

The issue of food claims has been discussed in Sweden for a longer time than most other European countries. Since 1990, Sweden has had a voluntary code in place – a self-regulating programme for health claims – and has therefore gained considerable operational experience compared to other European countries. At the present time, discussions are ongoing regarding a potential extension of the existing code also to include product specific health claims. The outcome of these discussions remains unclear. Ethical claims are about to gain public interest but have until present only received limited attention. Sweden would welcome new initiatives from the EU Commission regarding claims and would like to make the issue a higher priority.

B. MEMBER STATE POLICY

Swedish policy thinking on nutritional and health claims is based on consumer protection (not misleading of the consumer), combined with consumer safety and the promotion of healthy eating habits. Unlike at the EU level, the Food Act defines the term food as any foodstuff, beverage, stimulant or other product intended for human consumption, with the exception of products covered by the Act on Medicinal products. Consequently, there is a general prohibition on claims implying that food products can prevent or cure a disease.

1. Nutritional Claims

Nutritional claims are defined in Swedish law. The Swedish definition is in complete accordance with the EU definition and with the Codex Alimentarius definition. Furthermore, the Codex "nutrient content claim", "comparative claim" and "nutrient function claim" are all accepted in Sweden.

There also exists an ordinance regarding the use of certain symbols. Known as the "key hole" symbol, which is a registered trademark, it can be used on a wide range of food products providing that they have a low fat content or a high dietary fibre content. This allows it to be classified as a nutritional claim, which is in accordance with Codex guidelines.

2. Health Claims

Health claims are not, strictly speaking, defined in the Swedish Food Act. However, an ordinance on the labelling and presentation of foodstuffs states that "labelling and methods used must not contain statements that the foodstuff prevents, treats or cures

disease", reflecting the spirit of Article 2 of EU Directive 79/112. However, the Swedish definition is more medicinal than that which is currently being elaborated at Codex (April 1999 draft guidelines). The Swedish Marketing Act also applies to health claims.

Following an intense national debate in the 1980s, it was considered that health claims used in a responsible way might be an important means to help in implementing the dietary recommendations. Consequently, the then Medical Products Agency decided in 1989 to no longer to apply medicinal product legislation to products commonly found on the dinner table. The condition being that no dosage is given in marketing of the product and that no information is given, which is used for medicinal products. This led to the food industry launching a set of rules for health claims (see below).

3. Ethical Claims

There is no legislation and/or legal definition of ethical claims in Sweden. However, claims are subject to general clauses regarding correctness, honesty and non-misleading information in the Marketing Act. The very recent government study, Märk Väl (label well), raised the issue of ethical labelling and recommended that with EU co-operation, work should be carried out on labelling which will enable consumers to avoid products which are manufactured by companies which behave unethically.

C. VOLUNTARY CODES OF PRACTICE

1. Health Claims

Established in 1990 and recognised by the authorities, Sweden is home to the oldest industry-led voluntary code, regulating health claims. A health claim is defined as an assessment of the positive health effect of a foodstuff, i.e., a claim that the nutritional composition of the product can be connected with a reduced risk of a diet-related disease. The claim must be based on the importance of the product in a balanced diet, and must be in line with official Swedish dietary recommendations.

The code is being "updated" with a new proposal to include product-specific claims, following the development of functional foods. Product-specific physiological claims must be documented by human studies; the study group must be representative; normal amounts of the product should be used, and the duration of the studies should be sufficient to show lasting effects. A pre-market review of the studies supporting the claim is to be carried out by specially selected, internationally reputed scientists. A special "Assessment Board for Diet-Health Information" will be established to follow up the marketing of every product with different kinds of health claims, having the possibility to impose a fine for transgression of the rules.

2. Ethical Claims

Whilst a number of ethical labelling schemes are in operation in Sweden, only the "Rättvis" (fairness) logo and organisation is generally recognised: although the market share of labelled products is still fairly low (1-2%), more than 10% of Swedish consumers are aware of the Rättvis logo according to the organisation. The Rättvis

logo used for coffee, tea and cocoa products and the organisation is working on including other product categories such as honey, bananas, chocolate, orange juice, etc. The logo is recognised by the authorities.

D. VERIFICATION SYSTEMS

In addition to specific relevant legislation, the Swedish Marketing Act provides the necessary legal structure. However, although the National Food Administration, or the Swedish Nutrition Foundations or the Consumer Agency can provide advice, guidelines, etc, there is no pre-clearance mechanism in place for labelling claims.

The municipal environmental and health protection administrations undertake post-clearance. In the large majority of cases, disputes are settled out of court, through the issuing of prohibitions or information orders. Cases can, nevertheless, be taken to court if necessary and, under the Marketing Act, a so-called market disturbance fee of up to a maximum of 10 percent of the company's turnover can, in theory, be levied. Any legal person – consumer or competitor – can take a complaint to the Consumer Agency or the relevant municipal authorities, whilst the burden of proof always rests with the legal person responsible for the marketing of the product.

E. MEANS OF COMMUNICATION

There are no differences in the applicability of the relevant legislation/guidelines regarding the means of communication.

F. CONSUMER PROTECTION

Consumer protection is at the forefront of Swedish policy as far as labelling is concerned. There is generally a good working relationship between authorities and consumer organisations. Recently, the Swedish Consumer Association filed a complaint to the Consumer Agency (it receives about 200 complaints a year mostly related to dietary supplements and natural remedies) regarding labelling of an ice-cream product. It is expected that such action might take place more frequently in light of new food products entering the market, which make marketing claims.

G. BARRIERS TO TRADE

It is fair to say that this is not a major issue of contention. However, it is worth noting that the Swedish National Board of Trade notes that voluntary labelling systems (e.g., relating to ethical labelling and the use of the Rättvis logo) may cause barriers to trade and that such systems should be harmonized internationally.

H. CASE LAW

Cases are dealt with in the administrative system rather than going to court and, there is very little case law at hand. On a number of occasions the National Food Administration and the Medicinal Products Agency have issued administrative orders to change existing marketing practices with reference to both misleading advertisement and the use of health claims.

I. STAKEHOLDER ANALYSIS

1. Government Authorities

- In essence, the authorities are not planning to take any action on nutritional claims. Rather, they recognise and support the voluntary code for health claims. Nevertheless, current policy thinking in Sweden clearly favours an EU based regulatory framework for health claims as stated in Sweden's comments to the EU Green Paper on food law. It has also been suggested that when Sweden takes over the Presidency of the EU on 2001, it will launch a health claims initiative. As regards ethical claims, there is a growing awareness that the issue needs to be addressed, but once again the Government's latest reaction suggests that it is looking to the EU to establish a framework.

2. Consumer Organisations

- The Swedish voluntary code for health claims is supported by the two main consumer organisations - the Swedish Consumers` Association and the Consumer Coalition. The Consumers` Association has also pronounced its support for the new proposal concerning product-specific physiological claims, at least for a trial period. The Association has sympathy for the stipulated rules relating to documentation for these claims. The Consumer Coalition is very positive towards the new proposal since this organisation generally holds the view that more (true) information should be passed on to consumers so that they can make informed purchasing decisions.

3. Industry

- There is no indication from industry that modifications are needed concerning nutritional claims. As far as health claims are concerned, the voluntary code is proving satisfactory and, indeed, a revised programme has been in force since January 1997 and a new proposal has been tabled to include product-specific claims. The National Food Administration is considering how it should react to the new proposal.

* * *

II. MEMBER STATE POLICY

A. DEFINITIONS OF CLAIMS

1. Nutritional Claims

Nutritional claims are defined in the Swedish Ordinance on Nutritional Declaration (SLV FS 1993:21: Statens livsmedelverks kungörelse med foreskrifter ich allmänna råd om näringsvärdes deklaration).

In § 5 it is said:

> *"A nutritional claim is defined as any representation or message which states, implies or maintains that a foodstuff has special nutritional qualities regarding the energy it gives, gives in increases or decreased degree, or does not give; or regarding the nutrients it contains, contains in increased or decreased degree, or does not contain."*

It is also mentioned that compulsory information on the quality or quantity of nutrients does not constitute a nutritional claim.

The Swedish definition of a nutritional claim is in complete accordance with the EU definition and with the Codex Alimentarius definition. The Codex "nutrient content claim", "comparative claim" and "nutrient function claim" are all accepted in Sweden.

2. Health Claims

Health claims are not explicitly defined in the Swedish Food Act, but the National Food Administration's Ordinance with Regulations and General Advice on the Labelling and Presentation of Foodstuff (SLV FS 1998:15: Statens livsmedelsverks kungörelse med föreskrifter om märkning och presentaion av livsmedel) states in §6:

> *"Labelling and methods used must not contain statements that the foodstuff prevents, treats or cures disease."*

This more implicit definition reflects the definition found in Article 2 of 79/112.

In the latest Codex definitions of health claims from April 1999 (still at discussion stage), two different definitions are used. It is interesting and important to note that neither of these definitions includes words like "preventing, treating or curing."

Consequently, a comparative analysis of the Swedish and the EU definition vis-à-vis the Codex definitions suggests that these are not really in accordance with each other, i.e. the Swedish and EU definitions are more "medicinal" than the Codex definitions.

3. Ethical Claims

No official definition for ethical claims exists.

B. LEGISLATION

1. Nutritional Claims

The regulatory framework for nutritional claims includes primarily:

- *The National Food Administration's Ordinance with Regulations and General Advice on the Labelling and Presentation of Foodstuff (SLV FS 1998:15) (Statens livsmedelsverks kungörelse med föreskrifter om märkning och presentaion av livsmedel), §5 deals with honesty and non-use of labelling and methods that may lead to misunderstanding….., and*
- *The Ordinance on Nutritional Declaration.*

The Council Directive 90/496/EEC on nutritional labelling is implemented in the Ordinance on Nutritional Declaration.

In a wider sense, the Swedish Marketing Act logically also applies to nutritional claims.

The National Food Administration has, in a separate piece of legislation, The Ordinance with Regulation and General advice regarding application of a certain symbol (SLV FS 1989:2), made rules for the use of a so-called "key hole" symbol. The symbol is registered as a trademark and may be used on a wide range of food products providing they have a low content of fat or a high content of dietary fibre. The use of the keyhole symbol can be classified as a nutritional claim, in accordance with the Codex guidelines.

2. Health Claims

Health claims legislation concerning food product and dietary supplements is contained in:

- *The National Food Administration's Ordinance with Regulations and General Advice on the Labelling and Presentation of Foodstuff (SLV FS 1998:15: Statens livsmedelsverks kungörelse med föreskrifter om märkning och presentaion av livsmedel), §5 as described above, and*
- *§6, as mentioned under section II A 2.*

In a general note to §6, it is specifically mentioned that the regulations in §6 permit the use of health claims covered by the rules in the food industry's programme as published in "Health Claims in the labelling and marketing of food products." (Amended by Ordinance SLV FS 1995:15).

The Council Directive 79/112 on Labelling of Foodstuffs is implemented in The National Food Administration's Ordinance with Regulations and General Advice on the Labelling and Presentation of Foodstuff (SLV FS 1998:15)

The Swedish Marketing Act is equally applicable to health claims. Health claims regulation is also in place for other product categories. For example, natural remedies are regulated by The Medicinal Products Act.

3. Ethical Claims

There is no specific legislation in place regarding ethical claims. However, any claim - including ethical claims - is subject to general clauses regarding correctness, honesty and non-misleading information in The Swedish Marketing Act.

C. EXISTING PROHIBITIONS, RESTRICTIONS AND EXEMPTIONS

Nothing to report.

D. POLICY DEVELOPMENTS AND STAKEHOLDERS' POSITIONS

1. Nutritional Claims

The essence of policy thinking regarding claims is related to consumer protection and non-misleading of the consumer. In relation to food products, the policy thinking further includes consumer safety, consumer health and the overall promotion of healthy eating habits. With regard to nutritional claims, the Swedish policy has, in general, been coherent with Codex guidelines and EU policies/directives.

All kinds of claims used, either in labelling or marketing, must be in accordance with the totality of relevant legislation - the main laws being the Food Act and The Marketing Act. Expressed in a simplified way, labelling is covered by The Food Act and marketing is covered The Swedish Marketing Act.

The nutrient content claim, the comparative claim and the nutrient function claim are generally administered according to the Codex Guidelines on Nutrition Labelling and Nutrition Claims. As such, information on generally accepted nutrient function effects may be given, provided no connection is made to disease and provided that the product contains a significant amount of the substance in question - generally 15% of the recommended daily intake.

2. Health Claims

As will be demonstrated below, health claims are in use in Sweden. As such, it might be useful to outline the historical background and thinking behind such claims.

The Food Act defines the term food as any foodstuff, beverage, stimulant or other product intended for human consumption, with the exception of products to which the Act on Medicinal Products (SFS 1992:859) is applicable.

The term medicinal product is used to describe products intended for administration to people or animals to prevent, detect, palliate, or cure disease or symptoms of disease, or to be used with similar intent (SFS 1992:859).

Due to legislation on medicinal products, there is a general prohibition on claims implying that food products can prevent or cure a disease. On the other hand, the background of the dietary recommendations is that certain dietary habits do help to prevent diet-related diseases. During the 1980s, there was an increasingly intense debate in Sweden whether it was reasonable to have, on one hand, official dietary recommendations aiming at preventing diet-related diseases and, on the other, a complete prohibition of any claim regarding even well-established and generally recognised diet-health relationships. It was also considered that health claims used in a responsible way might be an important means of helping to implement the dietary recommendations.

With this background, the National Board of Health and Welfare and the Drug Department (now the Medical Products Agency) decided in 1989 no longer to apply medicinal product legislation to products commonly found on the dinner table. The condition being that no dosage is given in marketing of the product and that no information is given, which is used for medicinal products.

It was against this background that the food industry - encouraged by the authorities - took the initiative to create a set of rules for health claims concerning labelling and marketing of food products.

The current policy thinking in Sweden is clearly in favour of an EU based regulatory framework for health claims as it has also been stated in Swedish comments to the Green Book on EU food policy/legislation. It has also been suggested that when Sweden takes over the Presidency of the EU in 2001, it will launch a health claims initiative.

The National Food Administration is considering how it should react to the new proposal regarding so-called "Product-specific physiological claims" which has been prepared by the parties behind the food industry's self-regulation programme for health claims. (More details may be found under the Section III - Voluntary Instruments).

3. Ethical Claims

The subject of ethical labelling is about to receive more public attention. Late in 1997, the government decided to carry out a study concerning problems regarding labelling and other consumer information in relation to consumer goods. The study was also aimed at drawing up proposals regarding principles for consumer information and labelling of consumer goods. The study, Märk Väl (label well), was published in February 1999 (SOU 1999:7, further information may be found at www.faktainfo.se). In the study, ethical labelling is described as taking a position in certain ethical questions.

The study contains no comprehensive discussion of ethical claims/labelling. In the conclusion, a number of proposals regarding future principles for labelling are suggested. One such proposal is related to ethical claims. It is stated that Sweden – within the framework of EU co-operation - should work towards a labelling system, which enables consumers to avoid products, which are against their own personal ethical convictions.

On a general note, the Ministry of Finance, of which the Swedish Consumer Agency is now a member, has recently published a book "Märk Väl" (label well) which analyses the entire area of consumer information regarding ordinary consumer goods. The analysis has made a list of proposals for further consideration, some of which are also relevant to the present report; for example, it recommends that all products should be marked with country of origin and with the date the product was produced.

It has also been proposed that Sweden within the framework of the EU should work for the most complete labelling of ingredients possible on pre-packaged food products. In this way, consumers may avoid products presenting a risk to their health or products that go against their ethical convictions. The Food Administration will be asked to consider the keyhole labelling and questions in relation to contamination and safety. It has further been suggested that the possibility for consumer organisations to take part in the work regarding labelling of consumer goods should be strengthened and that representatives from these organisations should get on the Board of relevant public agencies.

In a note relating to ethical labelling and the use of the Rättvis logo the Swedish National Board of Trade remarks that voluntary labelling systems may cause barriers to trade and that such voluntary labelling systems should be harmonized internationally as far as possible.

III. VOLUNTARY INSTRUMENTS USED

A. VOLUNTARY INSTRUMENTS IN PLACE

1. Nutritional

No voluntary instruments are in place.

2. Health Claims

The Swedish code "Health Claims in the Labelling and Marketing of Food Products: The Food Industry's Rules (Self-Regulating Programme)" was established in 1990, i.e. five years before Sweden's entry into the European Union. From 1 January 1997, a revised programme has been applicable.

A health claim is defined in the programme as an assessment of the positive health effect of a foodstuff, i.e. a claim that the nutritional composition of the product can be connected with a reduced risk of a diet-related disease. The claim must be based on the importance of the product in a balanced diet, and must be in line with official Swedish dietary recommendations. The claim must consist of two parts: information on diet-health relationships, followed by information on the composition of the product.

The two-step principle has been required by the authorities to make the code compatible with the general prohibition of health claims. According to §6 of the Ordinance on Labelling and Presentation of Foodstuffs, the labelling used must not

contain statements that the foodstuff prevents, treats or cures disease. The general advice given in §6, however, provides scope for the use of health claims: General advice: The regulations in §6 permit use of the health claims that are covered by the Food Industry's Self-Regulating Programme. Claims that a certain food product has specific health effects in itself are not allowed within the present programme.

The programme has four parts:

A. *Rules based on official guidelines and statements, subject to review and update following discussion with the relevant authorities*
B. *Expert advice from the Swedish Nutrition Foundation regarding the application of the code*
C. *Information activities from organisations and companies involved, and from the Swedish Nutrition Foundation; and*
D. *Evaluation*.

The programme is based upon the following eight well-established connections**:**

1. *Obesity and energy content*
2. *Cholesterol level in the blood and fat quality or some types of soluble, gel-forming dietary fibre*
3. *Blood pressure and salt (sodium chloride)*
4. *Atherosclerosis as related to factors decreasing blood cholesterol and blood pressure, and naturally occurring omega-3-fatty acids in fat fish and fish products*
5. *Constipation and dietary fibres*
6. *Osteoporosis and calcium*
7. *Caries and the absence of sugars and other easily fermentable carbohydrates*
8. *Iron deficiency and iron intake, including bioavailabilty aspects*

The claim must consist of two parts: information on diet-health relationships, followed by information on the composition of the product. For instance, a hypertension-salt claim could be made like this:

> *In high quantities, ordinary salt may increase the risk of high blood pressure. X has a low salt content.*

The parties, which signed the self-regulating programme, have in co-operation with the Swedish Nutrition Foundation formulated a proposal for an extension of the existing code to include "Product-Specific Claims." The proposal was published in June 1998 and is currently being discussed with authorities, the scientific community and consumer organisations.

The proposal, which can be regarded as an extension of and as a complement to the existing programme on generic claims in two steps, is of particular relevance to so-called "functional foods", i.e. foods with a positive health effect beyond basic nutrition.

According to the proposal, product-specific physiological claims must be documented by human studies showing the effects that are going to be claimed. The study group must be representative, normal amounts of the product should be used, and the

duration of the studies should be sufficient to show lasting effects. A pre-market review of the studies supporting the claim is to be carried out by specially selected, internationally well-reputed scientists in the field. It is suggested that such a group be established on the European level.

A special "Assessment Board for Diet-Health Information" will be established to follow up the marketing of every product with different kinds of health claims, having the possibility to impose a fine for transgression of the rules. The Swedish Nutrition Foundation should continue its advisory role and may also have an administrative role in the pre-market scientific evaluation of studies.

3. Ethical Claims

The International Fair Trade Labelling Organisation (FLO) is represented in Sweden by the Rättvis organisation since 1996. "Rättvis" can be translated as "fairness" and the organisation has its own logo.

As with all member organisations of the FLO, the Rättvis organisation has similar principles and criteria for its work and licensing schemes, i.e. for small farmers: democratic forms of organisations, no discrimination, political independence, good product quality; and for employees: fair salaries, the right to organise itself, no child labour, etc.

The Rättvis logo used for coffee, tea and cocoa products and the organisation is working on including other product categories such as honey, bananas, chocolate, orange juice, etc. The market share of labelled products is still fairly low (1-2%). However, according to the organisation, more than 10% of Swedish consumers are aware of the Rättvis logo. Some of the bigger retail chains have started using the logo on some of their private brands.

About fourteen organisations (mainly NGO organisations) back the Rättvis organisation. The Swedish Development Agency, Sida, also gives financial support.

Another voluntary ethical label is used in Sweden, i.e. an "animal/rabbit" logo together with the text "against animal experiments." This labelling guarantees that the products or the ingredients in question have not been tested on animals. The label is used - among other things - on the products manufactured by the retail chain "The Body Shop."

Other ethically based labelling systems, e.g. the Rugmark, Clean Clothes Campaign and others are not really used to any extent.

B. DEFINITIONS USED IN THE VOLUNTARY INSTRUMENTS

1. Nutritional Claims

Not relevant.

2. Health Claims

As cited under Section III A, the food industry's self regulating programme defines a health claim as an assessment of the positive health effect of a foodstuff, i.e. a claim that the nutritional composition of the product can be connected with prophylactic effects or the reduced risk of a diet-related disease.

3. Ethical Claims

Not relevant.

C. EXISTING PROHIBITIONS, RESTRICTIONS AND EXEMPTIONS

1. Nutritional Claims

Not relevant.

2. Health Claims

Based on the fact that there is no consensus and thus no official recommendation on the use of probiotic products, claims on probiotic products were explicitly prohibited from being included in the revised programme of 1997 on health claims. Therefore, claims cannot be made according to the required two-step principle. Furthermore, health effects of probiotic microorganisms are confined to specific species - a fact that is frequently pointed out in the marketing of these products.

However, health benefits of probiotic products may be claimed if the product is registered as a natural remedy under the Medicinal Products Agency.

As an exemption, it is relevant to notice that in spite of the emerging consensus on the decreased risk of several cancers with a diet rich in vegetables and fruits, no diet-cancer claims are allowed in the Swedish code at present. The main reason is that since the protective effects cannot be connected with a certain component, such claims cannot be made according to the two-step principle.

3. Ethical Claims

Not relevant.

D. VOLUNTARY INSTRUMENTS ACCEPTED/RECOGNISED BY THE AUTHORITIES

1. Nutritional Claims

Not relevant.

2. Health Claims

The food industry's self-regulating programme is accepted/recognised by the authorities. In §6 of the Ordinance on Labelling and Presentation of Foodstuffs scope

is provided for the legal use of health claims that are covered by the mentioned self-regulating programme.

3. Ethical Claims

The Rättvis logo/claim is recognised by the authorities.

IV. VERIFICATION SYSTEMS

A. CRITERIA FOR SUBSTANTIATING CLAIMS

1. Nutritional Claims

The criteria for using nutritional claims are based on the relevant legislation and guidelines mentioned under II C 1, reflecting the 90/496/EEC Directive and Codex.

As mentioned earlier, any claim appearing on labelling, etc. makes nutrition labelling compulsory. As far as the allowed nutritional claims are concerned, i.e. content and comparative claims, these are based on quantitative criteria thereby making it relatively easy to verify if such claims are justified.

As far as the mentioned nutrient function claim is concerned these are allowed when they refer to generally accepted nutrient function effects (these are defined by a group of experts on Diet, Exercise and Health associated with the National Food Administration) and when they make no reference to disease.

2. Health Claims

Health claims must follow the eight well-established diet-health connections and the two-step principle outlined in the self-regulating programme.

As far as the new proposal (for product-specific physiological claims) is concerned a separate verification system is contained in the proposal as discussed under Section III A 2.

3. Ethical Claims

The voluntary scheme named Rättvis has its own set of principles and criteria applying to the whole food value chain. The scheme also operates its own verification/control system. The FLO Register Committees monitor compliance. No national authorities are involved.

B. LEGAL/ADMINISTRATIVE SYSTEMS FOR VERIFYING CLAIMS

General rules concerning labelling and marketing including claims are covered by the Swedish Marketing Act. The Consumer Agency and the Consumer Ombudsman, who also acts as the Director-General of the Consumer Agency, administer this act.

Section 6 of the Marketing Act concerning misleading advertising is particularly relevant in relation to claims.

As mentioned under Section II B, claims relating to food products are generally regulated by the Food Act and the National Food Administration in relation to labelling whereas marketing falls under the jurisdiction of the Swedish Marketing Act/ the Consumer Agency.

1. Pre-Clearance Rules/ Guidelines

Questions from companies about food legislation including claims may be addressed to the company's supervisory authority, which is usually the municipal environmental and health protection administration.

The National Food Administration publishes regulation, general advice, etc. and gives answers to principally important questions on interpretation and application of the legislation. However, no real pre-clearance mechanism exists.

Advice on claims and, in particular, on health claims is available from the Swedish Nutrition Foundation.

Several other central authorities, including the Consumer Agency and trade organisations, can also be contacted with questions relating to labelling and marketing.

2. Post-Clearance Rules/ Guidelines

Both the Swedish Food Act and the Swedish Marketing Act contain rules prohibiting incorrect labelling and misleading marketing.

In most cases where the regulations are not complied with they are settled in out-of-court procedures. Otherwise, cases can be taken to the civil court and the Market Court and only exceptional cases will invoke criminal responsibility. The Market Court is regarded as the supreme authority as far as laws relating to competition and marketing are concerned. It is the last resort.

Most cases are settled by issuing prohibitions or information orders.

C. LEGAL PERSONS ENTITLED TO TAKE LEGAL ACTION

Any legal person including consumers or competitors can complain to the Consumer Agency or the municipal authority regarding labelling or marketing not in accordance with the regulations.

D. BURDEN OF PROOF

The burden of proof always rests with the legal person responsible for the marketing of the product and no specific kind of proof is adduced.

E. APPLICABLE PENALTIES

Applicable penalties when violating claims regulations are usually of a limited size. Since 1996, the Marketing Act also includes some detailed rules prohibiting certain marketing activities, which in theory would cover claims. Violations thereof may cause a company to pay a so-called market disturbance fee (from a minimum 5.000 Skr (approx. EUR 800) up to 5 million SKr. (approx. EUR 800 000) or a maximum of 10% of the company's turnover.

V. CASE LAW

Decisions of the Market Court in 1992, (1992:18):

- *The decision concerned Sodium reduced salt/Mineral salt (sodium partly replaced with potassium), claiming that the product would prevent from CHD. The Market Court judged that it was a forbidden claim*
- *Moreover, the marketing company was not allowed to claim that ordinary salt has a blood pressure elevating effect, that potassium counteracts blood pressure increase, that potassium is healthy, that this particular sodium reduced salt is healthier than ordinary salt, that medical experts recommend this particular sodium reduced salt for the prevention of high blood pressure*

Decision of the Market Court in 1995:

- *The decision concerned the company Naturpost AB that was fined 500.000 SKr (approx. EUR 80 000) for violating the Marketing Act and the prohibition regarding health claims for natural remedies and dietary supplements.*

On a number of occasions the National Food Administration and the Medicinal Products Agency have issued administrative orders to change existing marketing practices with reference to both misleading advertisement and the use of health claims.

One such area has been claims relating mainly to dairy products containing probiotics.

Overall, cases are dealt with in the administrative system rather than going to court.

In May 1999, the Swedish Consumer Association filed a complaint with the Consumer Agency regarding the marketing of a new ice-cream product "godhälsa" (good health). In the complaint, it is stated that the advertising goes against the Marketing Act, the EU Labelling Directive and the food industry's self-regulating programme. This incidence is mentioned here to illustrate that the consumer organisation is concerned about misleading advertising.

VI. MEANS OF COMMUNICATION

No differences exist in the applicability of the relevant legislation/guidelines regarding the means of communication used such as television, Internet, press, labels,

etc. However, labelling is mainly regulated by the Food Act and marketing mainly by the Marketing Act.

VII. STATISTICS ON CLAIMS

The Consumer Agency receives approximately 200 complaints annually relating to claims; mostly these complaints concern dietary supplements and natural remedies. No further information is available. Out of approximately 200 complaints annually approximately 75 concern dietary supplements, approximately 40 slimming products and only a limited number concern nutritional/health claims for ordinary food products.

VIII. ANNEXES

1. Swedish Ordinance on Nutritional Declaration (SLV FS 1993:21) (Statens livsmedelverks kungörelse med foreskrifter och allmänna råd om näringsvärdes deklaration)
2. Ordinance with Regulations and General Advice on the Labelling and Presentation of Foodstuff (SLV FS 1998:15) (Statens livsmedelsverks kungörelse med föreskrifter om märkning och presentaion av livsmedel)
3. Health claims in the labelling and marketing of food products, The Food Industry's Rules (Self-Regulating Programme), Revised Programme, August 28, 1996, Applicable from January 1, 1997, The Swedish Nutrition Foundation
4. Health claims in the labelling and marketing of food products, The Food Industry's Rules (Self-Regulating Programme), Proposal for extension of the programme, Product-specific physiological claims, The Swedish Nutrition Foundation
5. The Swedish Marketing Act, Ministry of Public Administration Ds 1996:3

IX. DATABASE OF CONTACTS

P. UNITED KINGDOM

I. EXECUTIVE ANALYSIS

A. INTRODUCTION

In carrying out the necessary research for this report, Hill and Knowlton has contacted, spoken, met and discussed the development of public policy on claims with a variety of government departments, industry association, consumer organisations, scientific experts and self-regulatory bodies. Without exception, the people that we have contacted have been exceptionally helpful in assisting us with our research. As far as possible, we have sought to canvass the views of all organisations with an interest in these issues.

The organisations we met welcomed DG XXIV's initiative to undertake an examination of the regulatory framework for claims. However, there exist considerable differences of attitude towards the Commission proposing EU level initiatives. These are examined further in the report.

One of the most striking aspects of our research has been the spirit of co-operation and constructive dialogue that exists in the UK. Despite differing views on claims, there appears to be a genuine desire among all the constituents in the debate to reach common accord on a regulatory framework for claims. The Joint Health Claims Initiative is the prime example of this. This can only be seen as a positive development and can only lead to the creation of a system where levels of consumer protection are ensured whilst allowing industry to develop and market innovative products within a clearly defined regulatory framework. The involvement of the enforcement authorities, in particular the Local Authorities Co-ordination Body on Food and Trading Standards (LACOTS), is a groundbreaking step that should, in the long term, benefit all interested parties.

The platform for a frank exchange of views, mixed with a desire to reach agreement despite different positions, is a model that should be mirrored not only in other Member Sates but at the EU level as well.

B. MEMBER STATE POLICY

1. Nutritional Claims

The definition of nutritional claims in the UK is the same as defined in EU law in Directive 79/112. The UK authorities consider current nutritional legislation satisfactory and have no intention to amend/update (save for issuing guidelines on use).

2. Health Claims

Heath claims are regulated by reference to the various legislative instruments, which exist for food safety and labelling. There is no specific definition or legislation for health claims. However, although there are no plans to do so, the UK government would like to see specific legislation on health claims. They would prefer an EU initiative based on the current Codex Alimentarius draft guidelines, and are urging the EU Executive to take action. In the meantime, they have welcomed the Joint Health Claims Initiative (JHCI). However, the government recognises that non-UK products would not be covered by the JHCI nor does it believe that self-regulation alone is the best approach. It is also sensitive to calls from consumer organisations for a system of pre-vetting but equally aware of the increased bureaucracy that would result from compulsory pre-vetting.

Despite the lack of definition, health claims are generally understood to be any statement, suggestion or implication in food labelling or advertising that a food carries a specific health benefit, but not nutrition claims nor medicinal claims (i.e. claims that a food is capable of curing, treating or preventing a human disease or any reference to such a property).

3. Ethical Claims

In contrast to the above, the government does not seem under pressure to do anything with regard to ethical claims. Rather it believes that the current legislation in place (rules on misleading advertising or on trade descriptions) more than suffices. Furthermore, the Department of Trade and Industry (DTI) is a strong supporter of self-regulation and has thought of setting-up a self-regulatory code for on-pack ethical claims with retailers. However, due to the high level of fragmentation of the industry, the practicalities of enforcing a code would be very difficult.

C. VOLUNTARY CODE OF PRACTICE

Voluntary codes of practice for the means of communication are dealt with under a separate section.

1. Nutritional Claims

In order to supplement food labelling legislation, the Food Advisory Committee, an independent body which provides government with advice on food regulation, issues guidelines on nutritional claims. These guidelines are updated on a regular basis.

Industry organisations have also developed their own codes of practice on nutritional claims. The most notable of these is the guidelines drawn up by the Co-operative Wholesale Society (CWS).

2. Health Claims

The Joint Health Claims Initiative (JHCI) is the principle voluntary code of practice in the UK. This has been developed by industry, consumer organisations and the enforcement authorities.

The majority of stakeholders in the UK are hoping that the Joint Health Claims Initiative (JHCI) will provide the necessary framework for regulating health claims. However, a number of the participants believe that it is a stopgap until a proper legislative framework, which should emanate at EU level, is established. The JHCI can claim that all interested parties (government, enforcement authorities, consumers and industry) participated actively and they are now hoping that it will come into force in 2000. A Code Administration body, made up of a Council (representing all key stakeholders), a Secretariat and an expert authority will manage the JHCI. Consumers, especially, hope that the soon to be created Food Standards Agency will take responsibility. The initiative promotes a pre-market advice/pre-vetting system, which suggests the exercise of due diligence, applied to health claims in all means of communications, with the overriding principle that the likely consumer perception of the health claim is paramount. The Code administration body will develop a list of generic health claims, to be approved by the Expert authority, to be reviewed regularly. A system of innovative claims will also be established. Whilst not legally binding, it promises to deliver.

Under the JHCI code, annex 1 (see Section VII) sets out the limits between what is considered to be a health claim and a medicinal claim. It also treats the issue of borderline cases. The code, therefore, provides guidance on how a legally acceptable claim may be made for a food, which has a role in reducing the risk of disease.

In practice, the involvement of the enforcement authorities in the JHCI will give the initiative a form of official backing. The enforcement authorities are represented by the Local Authorities Coordinating Body on Trading Standards (LACOTS) and have been closely involved in the drafting of the code and will provide representatives for the JHCI Council. However, despite the involvement of LACOTS, it will remain up to individual local authorities, which are responsible for enforcing relevant legislation to decide whether to prosecute on a case by case basis. In practical terms, it should be noted that LACOTS welcomes the JHCI because it will remove an element of subjectivity from enforcement through the establishment of a list of generic health claims. LACOTS will advise Local Authorities to use the JHCI as guidelines for their activities. They also hope that the Code Administration Body will, in effect, be a substitute for court proceedings, which would only need to be used as a last resort.

The Co-Operative Wholesale Society (CWS) has developed its own code of practice for labelling of pre-packed foods for both nutritional and health claims. They have established a consumer help line, a complaints and disputes structure and a jury. The code builds on the Food Labelling Regulations and the FAC guidelines. The views of the CWS on nutritional claims is that the lack of detailed provisions has led to a situation where labelers make factually correct claims, which show their products in the best light. However, because different criteria have been used in different product sectors, the potential for misleading consumer arises. Consequently, the CWS Code provides for a number of rules. For health claims, the CWS states that “modern technology increasingly allows foods to be manipulated to deliver health benefits”. The absolute ban on referring to diseases prohibits effective consumer communication by at best, forcing labelers to adopt less direct messages, at variance with generally accepted health messages and failing to capitalize on the benefits of short, sharp messages often repeated. At worst, it discourages claims all together.

3. Ethical Claims

In the UK, there are a number of organisations that are involved in ethical trading but relatively few, which have specifically established voluntary codes on ethical claims. Nevertheless, there could be growing pressure from members of the voluntary codes to use these as a basis for making ethical claims.

The Fairtrade mark appears to be the exception in the UK and is one of the few examples of a voluntary agreement on ethical claims. The Fairtrade mark provides an independent mechanism for assisting disadvantaged producers of specific commodities in developing countries by defining criteria for eligible producers and for terms of trade, establishing a register of qualifying producers, and monitoring transactions so as to provide a guarantee to consumers that products bearing a Fairtrade Label meet the agreed criteria. The Fairtrade Foundation, which has set up a licensing system for companies that wish to use the Fairtrade Mark, grants the right to use the Fairtrade mark on or in relation to products subject to the licensee complying with the terms and agreement of the license.

However, the lack of definition of claims and the ability of manufacturers of products to place their own claims on products could lead to consumers being misled. The lack of any system of control leaves the market for ethical claims open to potential abuse.

D. VERIFICATION SYSTEMS

UK law does not as such provide an inventory of criteria for substantiating nutrition, health or ethical claims. It is up to the courts to decide whether or not a particular claim contravenes the law. Responsibility for enforcing the law falls to the local authorities. The Fairtrade Foundation does, however, have a list of criteria that a manufacturer must meet in order to qualify for the Fairtrade mark. Once again, there are no pre-clearance requirements in law although the JHCI encourages manufacturers to seek pre-clearance. All the organisations that administer the means of communication encourage pre-clearance for all types of claims. Some do this more than others; for example, given the costs involved, it is a normal procedure for television adverts. As to post-clearance, the Director-General of the Office of Fair Trading has the power to stop an advertisement by means of a court injunction. However, this is only used in exceptional circumstances and once self-regulatory channels have been exhausted.

As is demonstrated above, the legislative measures in place in the UK all require the enforcement authorities to prove that any particular claim that is being made is contrary to the provisions of the various rules in force.

In the case of the Trade Descriptions Act, the Food Labelling Regulations and the Food Safety Act, the offences are criminal offences and, therefore, the burden of proof is “beyond reasonable doubt”. In the case of the Control of Misleading Advertising Regulations the Director-General would need to show that a claim is misleading on the “balance of probabilities”.

This has repercussions for the decision by the enforcement authorities to take action against makers of claims, in particular where there is contradictory scientific evidence on a specific claim.

E. CONSUMER PROTECTION

The issue of consumer protection as regards claims is a priority concern of many consumer organisations and, indeed, the authorities. This is reflected by the detailed and carefully worked out positions of the Consumer Association (CA) and the Consumers in Europe Group (CEG).

The CA, provides numerous examples of lack of consumer protection from nutritional claims, e.g. Hala Caramel Heaven bar claims to be 85% fat free, which means is still contains 15% fat which is still a significant amount of fat.

In their opinion, most claims are not regulated and, therefore, their use can often be inconsistent, confusing, or even misleading. They have consequently proposed four recommendations, which can be summarised as:

1. Definitions should provide criteria for absolute and relative claims for nutrients relevant to dietary guidelines;
2. The use of nutrition claims that are not relevant to the UK population should be prohibited;
3. Any nutritional claim should be supported by a full nutrition panel, in the absence of mandatory nutrition labelling; and
4. A set of standard criteria for healthy eating symbols should be developed that applies across the board and a nationally agreed set of nutrition criteria should be agreed for all healthy eating schemes.

The CEG have developed three specific recommendations:

1. CEG believes that nutrient content claims must be clearly defined in terms of the quantitative level of the nutrient present, be consistent between products, and be meaningful to consumers.
2. The Scientific Committee for Foods should be responsible for drawing up threshold values for individual nutrients based on the most up-to-date research.
3. CEG is opposed to the use of implied nutrient content claims.

As regards health claims, the position of the consumer organisations is detailed and very well documented, reflecting the importance of the issue. There is also a general view in government departments that there is a lack of consumer protection. The CA has elaborated four reasons for this, namely:

1. An increasing number of products are being marketed on the basis that foods can play a role in the protection and promoting of health.
2. These claims are not always explicit, often implying health benefits through the use of packaging and illustrations.
3. The difference between a health and medicinal claim is not always obvious to consumers.

4. As there are currently no regulations covering health claims, an increasing variety of complex claims are now being made on product labels.

Given the above and the fact that research has demonstrated that consumers have little faith in health claims, the CA concludes that effective legislation is required. Such legislation should address the issue of a proper definition for health claims, the conditions of use, a prior approval system, rules relating to the required evidence (scientific), and a system of penalties.

In the absence of legislation, certain consumer groups welcome the JHCI in the short term and acknowledge that the Code of Practice might provide a basis for control. Industry's position on health claims is essentially enshrined in the JHCI, although the Food and Drink Federation goes a step further in calling for disease risk reduction claims to be allowed, pointing out that Directive 65/65 is no longer appropriate in today's environment when it is acknowledged that a food can be beneficial to a person's health.

F. BARRIERS TO TRADE

Generally, the problem of barriers to trade is not associated with claims. There are, nevertheless, concerns that if the use of health claims continues to grow, this might accentuate the problem. The Medicines Control Agency did, however, give specific examples of barriers to trade problems in connection with borderline cases between a food and a medicine and on the different interpretations given by Member States to 65/65. The same applies to the various interpretations given to 79/112 and, in particular, Article 2. Some Member States have a more liberal view of this while others adopt a more narrow interpretation. This can lead to differences between Member States and the need for manufacturers to adapt a claim used in one country for another market. However, can this be seen as a barrier to trade? There is an industry view, which acknowledges that they have to adapt to each national market – taking into account national cultural/social differences, just as they have to change the language of the claim.

One of the objectives in the JHCI is "promoting consistency in the use of health claims in the UK, Europe and internationally". The JHCI code has had to be notified to the European Commission under the Directive 83/189 on national rules affecting the free movement of goods. This will provide both the Commission and other Member States an opportunity to indicate whether they believe that the code will result in barriers to trade.

From our discussion, it appeared more likely that barriers to trade would arise from claims that are approved under the code in the UK but forbidden elsewhere in Europe. There was a general view that mutual recognition of a code would prove difficult and the authorities also pointed out that claims from outside the UK would not fall under the code.

G. MEANS OF COMMUNICATIONS

The means of communication in the UK system of regulation is notable in its reliance on self-regulation. The arguments in support of such an approach are clearly demonstrated by the professional and effective system that has been established.

For broadcast communications claims are regulated through the Independent Television Commission (television advertisements) and the Radio Authority (radio advertisements). Both these bodies have been set up under the broadcasting act with a requirement to develop and enforce codes of practice. To assist them with their task clearance bodies have been created for both television (the Broadcasting Advertising Clearance Centre) and radio (the Radio Advertising Clearance Centre). They provide pre-market advice to advertisers on the legality of advertising copy.

For non-broadcast advertising a similar system exists but takes account of the very different nature and scale of non-broadcast advertising. The British Codes of Advertising and Sales Promotion are drafted by the Committee on Advertising Practice (CAP). The Advertising Standards Authority provides independent scrutiny of the self-regulatory system administered by CAP and is the responsible for consumer complaints.

For both broadcast and non-broadcast advertising the respective codes detail provisions specifically related to health claims (in the case of the radio, health claims must receive pre-clearance).

H. CASE LAW

There is a limited amount of case law available on claims in the UK. The reasons for this appear to be threefold:

- The UK system of regulation is heavily based on self-regulation and, therefore, disputes tend to be resolved outside the legal system. This is particularly the case with regard to the regulation of the means of communication.
- Even where there are specific legislative provisions on claims, the system is such that the parties are encouraged to reach an agreement outside the courts.
- The authorities responsible for the enforcement of legislation are the local authorities. There is reluctance on the part of the local authorities to bring cases before the courts. This is due to a number of reasons but the most important appears to be cost and the difficulties in securing a judgement as a result of the burden of proof being on the plaintiff to show that the claim is not justified.

There is considerable evidence to suggest that the lack of resources available to local authorities results in a number of claims being made that would otherwise be unlawful. We are not in a position to judge whether this has the direct effect of a lack of consumer protection.

LACOTS has provided us with a summary of a study carried out by local authorities in Wales that assess whether claims comply inter alia with the Food Labelling Regulations 1996.

This study would seem to imply that a number of claims are being made that in the judgement of the local authorities are unlawful. The summary of this study is provided in annex XII.

I. STAKEHOLDER ANALYSIS

The regulation of claims, and specifically health claims in the UK is noteworthy in that there is heavy reliance on self-regulation - particularly in the means of communication. The Joint Health Claims Initiative should also be highlighted, although the parties concerned are still "wondering" whether it will be successful.

1. Government Authorities

- On nutrition claims, the government does not perceive the need for a review of EU legislation. However, the FAC guidelines are regularly updated.

- On health claims, despite the support that the government has expressed for the JHCI, they are committed to an EU level initiative in this area.

- No real position on ethical claims exists within government, only that ethical claims must comply with rules on misleading trade descriptions.

- The enforcement authorities welcome the JHCI as a means to assist them in work on health claims. No specific positions on nutritional or ethical claims were expressed.

- The enforcement authorities are hampered by a lack of resources and the current structure of the regulatory framework that requires them to prove that a claim is not justified. As a result, they strongly support the Joint Health Claims Initiative, as this will act as a filter on claims that are currently made but fall outside the law.

2. Consumers

- Consumer organisations believe that nutritional claims can still mislead consumers and that further regulation is necessary. In particular, they wish to see criteria for absolute and relative claims, a full supporting nutritional panel and a set of standard criteria for healthy eating symbols.

- Despite the JHCI, consumer organisations still favour a legislative framework specific to health claims (some remain opposed health claims in principle). They believe that this should be in the form of a European Union Directive and that pre-market clearance of claims is necessary. However, consumer organisations did not necessarily see the Misleading Advertising Directive as the only vehicle to regulate claims. They are, however, concerned that there is a danger of the consumer is being misled in the current regulatory environment. However, in the absence of EU legislation they are supporting the Joint Health Claims Initiative.

3. Industry

- In contrast to the position of the consumer associations, industry favours the self-regulatory approach and believes that it should be left up to the makers of claims to decide whether pre-market clearance is necessary. They believe that makers of claims should be allowed to use claims as long as these claims may be justified. The onus should be on the maker of the claim to justify.

- Under current legislation, the onus is on the enforcement authorities to prove that the claim is not justified. Industry would also like to see changes to Directive 65/65 and 79/112 to allow disease risk reduction claims to be made. However, industry remains skeptical of EU legislative solutions. It is concerned that an EU directive would result in the lowest common denominator approach and, therefore, restrict marketing freedoms.

4. Self regulatory bodies

- The organisations that regulate the means of communication are firmly opposed to EU legislation and point to sophisticated and efficient systems that exist in the UK.

In summary, the situation in the UK is as follows:

- Nutrition claims – despite concerns from the consumer associations, a clear regulatory framework, which has the support of industry government, is in place. The framework is updated to reflect changes in scientific knowledge.
- Health claims – if the JHCI proves successful the need for legislation may be limited. However, both government and consumers and the enforcement authorities would welcome, at a minimum, a set of regulatory principles for health claims.
- Ethical claims – there is no comprehensive approach to ethical claims. There is a danger that consumers may be misled. However, the solutions that need to be adopted are likely to be very different from those required for health or nutritional claims.

* * *

II. MEMBER STATE POLICY

A. DEFINITIONS OF CLAIMS

1. Nutritional Claims

The definition of a nutritional claim is set out in the Food Labelling Regulations 1996 and is as follows:

"any statement, suggestion or implication in any labelling, presentation or advertising of a food that a food has particular nutrition properties"

Nutrition properties is defined as:

"(a) the provision (including provision at a reduced or increased rate), or lack of provision, of energy" or "(b) the content ((including content in a reduced or increased proportion), or lack of content of any nutrient (including any substance which belongs to, or is a component of, a nutrient)."

The definition of nutritional claims is as in the Directive on the Labelling of Foodstuffs (90/496).

Article 40(2) of the Food Labelling Regulations 1996 provides:

"a claim of the type described in part II of Schedule 6 shall not be made, either expressly or by implication, in the labelling or advertising of a food, except in accordance with the appropriate conditions set out in that Part of that schedule."

Part II of Schedule 6 provides a list of types of claims that can be made. Alongside the types of claims that are allowed the conditions that must be met are listed: The types of claims that are permitted are defined as follows:

- "Claims relating to foods for a particular nutritional uses" – A claims that a food is suitable, or has been specifically made, for a nutritional purpose.
- "Reduced or low energy value claims"- a claim that a food has a reduced or low energy.
- "Protein claims" – a claim that a food, other than a food intended for babies or young children which satisfies the conditions of item 1 of this Part of this schedule, is a source of protein.
- "Vitamin claims" – a claim that a food, other than a food intended for babies or young children which satisfies the conditions of item 1 of this part of this Schedule, is a source of vitamins.
- "Mineral claims" – a claim that a food, other than a food intended for babies or young children which satisfies the conditions of item 1 of this Part of this Schedule, is a source of minerals.
- "Cholesterol claim" – a claim relating to the presence or absence of cholesterol in a food.
- "Nutrition claim" – any nutrition claim not dealt with under any other item in this part of this schedule.

The definition provided in the Food Labelling Regulations 1996 are supplemented by guidelines based on recommendations made by the Food Advisory Committee (see Section III.A.1).

2. Health Claims

The UK has no legal definition of a health claim.

However, for working purposes the government considers that health claims are any statement, suggestion or implication in food labelling or advertising that a food carries a specific health benefit, but not nutrition claims nor medicinal claims (i.e. claims that a food is capable of curing, treating or preventing a human disease or any reference to such a property). The term "health claim" includes claims, which refer to nutrient function (e.g. calcium aids the development of strong bones and teeth) and to recommended dietary practice (e.g. eat more oily fish for a healthy lifestyle).

3. Ethical Claims

There is no legal definition of an ethical claim in UK law.

B. LEGISLATION IN PLACE

1. Nutritional Claims

The main piece of legislation in place in respect to nutrition claims in the UK are the Food Labelling Regulations 1996 (see annex I). These include the definition of a nutrition claim as provided for in Directive 90/496.

The Food Labelling Regulations contain the legal definition of a nutrition claim and set out conditions for their use, including the requirement to provide nutrition information if a claim is made.

2. Health Claims

Although no specific legislation exists, health claims must comply with a variety of legislative measures including the Food Labelling Regulations, the Food Safety Act (see annex II), the Trade Descriptions Act (see annex III) and the Control of Misleading Advertising Regulations (see annex IV).

The Control of Misleading Advertising Regulations implements Directive 84/450 on Misleading Advertising.

Directive 79/112 on the Labelling of Foodstuffs is implemented inter alia by the Food Labelling Regulations.

In particular, Article 2 (para. 2) of Directive 79/112 is implemented by Schedule 6 Part I of the Food Labelling Regulations 1996.

Article 2 of the Directive (para. 1) is reflected in the Food Safety Act that provides that it is an offence to describe falsely a food or to mislead as to its nature, substance or quality.

3. Ethical Claims

There exists no specific legislation in the UK on ethical claims. In a similar way to health claims, ethical claims are, therefore, subject to general provisions on claims - in particular, the Trade Descriptions Act and the Control of Misleading Advertising Regulations.

C. EXISTING PROHIBITIONS, RESTRICTIONS AND EXEMPTIONS

1. Nutritional Claims

For each of the types of claims that are listed in Part II of Schedule 6 of the Food Labelling Regulations, specific conditions for their use are set out. Below we have set out the conditions for certain types of claims. A full list of the conditions, which each type of claim must meet, is provided in annex I.

a. Claims relating to foods for particular nutritional uses:

"1. The food must be capable of fulfilling the claim.

2. The food must be marked or labelled with an indication of the particular aspects of its composition or manufacturing process that give the food its particular nutritional characteristics.

3. The food-

(a) must be marked or labelled with the prescribed nutrition labelling and may be marked or labelled with further information in respect of either or both of –

(i) any nutrient or component of a nutrient (whether or not a claim is made in respect of such a nutrient or component) or

(ii) any other component or characteristic which is essential to the food's suitability for its particular nutritional use and

(b) when sold to the ultimate consumer, must be pre-packed and completely enclosed by its packaging"

b. Cholesterol claims

"1. Subject to condition 3 the food must contain no more than 0.005 per cent of cholesterol.
2. The claim must not be accompanied by a suggestion, whether express or implied, that the food is beneficial to human health because of its level of cholesterol.
3. If the claim relates to the removal of cholesterol from, or its reduction in, the food and condition 1 is not met, such claims shall only be made-

(a) as part of an indication of the true nature of the food.
(b) as part of an indication of the treatment of the food.
(c) within the list of ingredients, or

(d) As a footnote in respect of a prescribed nutrition labelling.

4. The food shall be marked or labelled with the prescribed nutrition labelling."

2. Health Claims

a. Food Labelling Regulations

The Food Labelling Regulations section 40 (1) provides that:

"A claim of the type described in Part I of schedule 6 shall not be made, either expressly or by implication, in the labelling or advertising of a food."

Schedule 6 provides the following:

"1. A claim that food has tonic properties

2. A claim that a food has the property of preventing, treating or curing a human disease or any reference to such a property."

b. Food Safety Act

In the UK, health claims are also subject to general provisions in the Food Safety Act 1990 (Section 15). This makes it an offence to describe falsely a food or to mislead as to its nature, substance or quality.

c. Trade Descriptions Act

Health claims are also subject to Section 1 of the Trade Descriptions Act 1968 which makes it unlawful to apply a false or misleading trade description.

d. Control of Misleading Advertising Regulations

Health claims are also subject to the Control of Misleading Advertisements Regulations 1988 (CMAR). Under CMAR, an advertisement is defined as "any form of representation, which is made in connection with a trade, business, craft or profession in order to promote the supply or transfer of goods or services, immovable property, rights or obligations".

Under CMAR, an advertisement is defined as misleading if in "any way, including its presentation, it deceives or is likely to deceive the persons to whom it is addressed or whom it reaches and if, by reason of its deceptive nature, it is likely to affect their economic behavior or, for those reasons, injures or is likely to injure a competitor of the person whose interests the advertisement seeks to promote."

3. Ethical Claims

There are no specific restrictions on ethical claims in the UK. However ethical claims are subject to general rules on misleadingness in the Control of Misleading Advertising Regulations and the Trade Descriptions Act and, where applied to foodstuff, to rules under the Food Safety Act (discussed above).

D. POLICY DEVELOPMENTS AND STAKEHOLDERS' POSITIONS

1. Nutritional Claims

In general, the UK authorities consider current legislation on nutritional claims to be satisfactory. They are happy with the manner in which nutritional claims are dealt with under EU law.

The UK government plans no new policy initiatives on nutritional claims. However, it should be noted that the UK government has consulted interested parties on the Food Advisory Committee guidelines. These will be issued shortly.

2. Health Claims

The UK Government's current policy on health claims is as follows:

"The UK government takes very seriously the need for accurate and informative food labelling. It therefore wishes to see claims made about health which are soundly based and do not mislead consumers. It believes that international agreement is the way forward on both health and nutrition claims, to ensure that all products on our shelves follow common standards. It supports the progress made by Codex Alimentarius and urges the European Commission to work on developing an EC claims policy based on Codex standards and to bring forward proposals as soon as possible."

The UK government cites two main reasons for the lack of a definition of health claims: (1) Health claims are regulated by the Food Safety Act 1990 in so far as they may be considered misleading claims (2) Health claims are a relatively new phenomena. Government policy is therefore still being developed.

In the UK, the government's policy on health claims is linked to a number of factors among which the most important are:

- UK regulation of food policy is undergoing a radical re-structuring. The UK government has decided to set up a dedicated Food Standards Agency (FSA). This will bring together different parts of the administration including parts of the Department of Health and parts of the Ministry of Agriculture Food and Fisheries. The FSA is expected to be up and running by April 2000. The FSA will be independent but under the political control of the Minister of Health.
- Medicinal claims for non-medicinal products are banned under UK law.
- In the interim period, and in the absence of EU legislation on health claims, the government is lending its support to the Joint Health Claims Initiative (JHCI) (see section on voluntary instrument for further details).

The UK government has, in fact, encouraged the development of the JHCI. However, the government's position remains that it would like to see legislation on health claims. In particular, the government recognizes that non-UK products will not be covered by the JHCI and believes that a consistent approach must be ensured.

The government does not believe that self-regulation will work for all manufacturers and recognises calls from consumer organisations for a system of pre-vetting of health claims. However, the government is equally aware of the increased bureaucracy that would result from a system of compulsory pre-vetting.

No new national policy initiatives are planned on health claims in the immediate future. However, the UK government has made it clear that it would like to see an EU initiative on health claims in the near future.

3. Ethical Claims

Responsibility for ethical claims does not fall under the responsibility of a particular department but is dealt with by both the Department for Trade and Industry and the Department for International Development.

The Department of Trade and Industry does not have a particular policy on ethical claims. However, they point out that any claim that is made for any product is subject to legislation covering claims such as rules on misleading advertising or on trade descriptions.

The UK government points out that it encourages a co-operative approach between industry, consumers and enforcement authorities. The policy of the Department of Trade and Industry is to leave the market to determine the regulatory framework subject to high levels of consumer protection and fair competition between providers. Regulations should be driven by consumer demand and the need for information and, in any case, should not be prescriptive. As such, the Department of Trade and Industry is a strong supporter of self-regulation. The Department of Trade and Industry has thought of setting up a self-regulatory code for on-pack claims with retailers. However, the industry is extremely fragmented and it would be extremely difficult to effectively enforce a code.

The Department of Trade and Industry is also responsible for the Internal Market and ensuring that there are no barriers to trade between the UK and other Member States. They would, therefore, examine policy developments in other Member States and at the European level in this context.

The Department for International Development believes that government policy will be dependent on consumer demand. However the Department for International Development is also aware that consumers can be very volatile in their reaction to ethical claims. The Department for International Development's priority is for ethical claims/standards to assist in the elimination of the problem identified (for example, poverty) and to educate consumers (for example, about the operation of globalisation) and to allow consumers to make informed choices.

There are no new initiatives planned by the government on ethical claims. At this stage, no particular government department seems to have responsibility for ethical claims. There is mixed responsibly in that the Department of Trade and Industry is responsible for advertising and consumer protection, while the Ministry for International Development is responsible for the types of policy issues that might be included under ethical claims, such as fairtrade.

However according the Fairtrade Foundation (see section on voluntary instruments) there are moves by DG VIII to develop a standard for fairtrade.

E. REMARKS ABOUT BARRIERS TO TRADE AND LACK OF CONSUMER PROTECTION

1. Nutritional Claims

No specific cases of barriers to trade as a result of nutritional claims were identified.

The Consumer's Association (CA) provides specific examples of a lack of consumer protection from nutritional claims. The CA general policy is that "whilst consumers value claims when making food choices, they expect them to be trustworthy! It is important that all claims are adequately controlled so that they are consistently used, meaningful and do not mislead".

In respect of nutritional claims they make the following points:

- Although some nutrient content claims have quantified legal definitions, the law only requires that the rest be capable of fulfilling the claims they make, and that they give prescribed nutrition labelling. A variety of claims are now made, together with retailers' own healthy eating logos and product ranges, promoting a healthier choice. The government's Food Advisory Committee (FAC) has produced guidelines on the use of terms such as "low fat" but these are not always followed.

- As most claims are not regulated, their use can often be inconsistent and confusing, or may even mislead.

The Consumer's Association, therefore, makes the following recommendations:

- Definitions should provide criteria for absolute and relative claims for nutrients relevant to dietary guidelines (including energy, fat, saturates, trans fatty acids, sugars, fibre, sodium, salt and relevant vitamins and minerals).
- The use of nutrition claims that are not relevant to the UK population e.g. high in thiamin, where there is no evidence of a likely deficiency or where these are no clear benefits to either increasing or reducing intake of the nutrient, should be prohibited.
- Any nutrition claim should be supported by a full nutrition panel (in the absence of mandatory nutrition labelling). Currently, a food carrying a claim that it is lower in fat or contains added vitamins or minerals, is only required to give the basic four panels (i.e. energy, carbohydrates, protein and fat). Full nutrition labelling would ensure that levels of sugars and sodium were always labelled.
- A set of standard criteria for healthy eating symbols should be developed that applies to all stores and sectors and used on own-label and branded products. Any symbols or logos used on foods to suggest a healthy or healthier product should only be used for an all-round healthy product. A nationally agreed set of nutrition criteria should be agreed for all healthy eating schemes.

Finally the CA points out that in the short term, industry should develop guidelines to ensure the consistent and responsible use of nutrition claims.

The Consumers in Europe Group (CEG), an independent voluntary UK organisation, concerned with the effects of EU legislation on UK consumers, makes the following recommendations in respect of nutrition claims.

- CEG believes that nutrient content claims must be clearly defined in terms of the quantitative level of the nutrient present, be consistent between products, and be meaningful to consumers.
- The Scientific Committee for Foods should be responsible for drawing up threshold values for individual nutrients based on the most up-to-date research.
- CEG is opposed to the use of implied nutrient content claims.

2. Health Claims

No particular barriers to trade were identified by the Department of Agriculture Fisheries and Food or by the Department of Health. However, they both recognised that barriers to trade could arise as the use of health claims develops.

The Medicines Control Agency did, however, give specific examples of barriers to trade. These barriers refer to borderline cases between food and medicines and focus on differing interpretations of Directive 65/65. A specific example that was cited concerns the classification of vitamins. In Germany, a product that contains one and a half the recommended daily allowance is considered to be a medicine. This is not necessarily the case in the UK. The MCA has, therefore, been requested to provide an explanation for this situation by the European Commission. In the UK the criteria for whether a product is considered a medicine is consumer safety. The MCA points out that in other Member States other factors are included. This can, therefore, give rise to barriers to trade.

There is a general feeling in government departments that there is a lack of consumer protection in health claims. This is echoed by the Consumer organisations. In particular, there is concern that claims may be misleading and may give rise to concerns about safety.

The Consumer's Association makes the following points with regard to consumer protection and health claims:

- An increasing number of products are being marketed on the basis that foods can play a role in protecting and promoting health.
- These claims are not always explicit, often implying health benefits through the use of packaging and illustrations.
- The difference between a health and medicinal claim is not always obvious to consumers.
- As there are currently no regulations covering health claims an increasing variety of complex claims are now being made on product labels.

The Consumer's Association makes the following recommendations in respect of health claims:

- Research shows that consumers currently have little faith in health claims on products. This points to the need for effective regulation.
- The JHCI (see section on voluntary instruments) should help improve the situation in the short term in the absence of legislation.

Legislation should address the following issues:

- Controls on the use of health claims should be tightened up so that consumers can trust valid claims that are made including:
  - The definition of a health claim;
  - Conditions for the use of a health claim;
  - Prior approval of claims before sale;
  - Rules on the level of evidence and standard of proof needed to make a claim; and
  - Development of a system of quick penalties when unsubstantiated, exaggerated or misleading health claims are used on foods.

- Health claims should only be used if approved in advance, with approval based on an independent and exhaustive review of scientific literature. Misleading claims need to be prevented rather than dealt with after products are on the market and have in some cases, already been heavily promoted.
- An expert Committee should have responsibility for advising on and monitoring the use of health claims. The Committee should consider when it is appropriate for a claim to be made e.g. the level of active ingredients, and the amount of product likely to be consumed.
- If a health claim is made, the manufacturer should be required to give additional information on the food label, including at least the following and any additional information that the expert committee thinks necessary about a specific product:
  - Amount of active ingredients, and information on how much needs to be taken to have the desired effect;
  - Origin of ingredients;
  - Warnings on contra-indicators for use if necessary or appropriate;
  - Full nutrition labelling, to ensure that consumers are given the full nutritional context in which the claim is made and are not misled about the overall health benefit of a product;
  - A statement of the role of the food in relation to the overall diet and other factors;
  - Nutrition criteria for making health claims should be established e.g. maximum fat, sugars, and sodium content etc.

The Consumers in Europe Group (CEG) makes the following recommendations in respect of health claims.

- Health claims include any statement, suggestion or implication in food labelling that a food is beneficial to health, other than nutrient content claims and medicinal claims.
- A number of different claims fall into this category including those describing food as "natural", "light/lite", "fresh" or "full of goodness". These can be particularly confusing and in many cases meaningless. They often imply that the product is a healthier version of a standard one but the difference is usually unspecified and unclear.

- CEG supports the position that any ambiguous or imprecise claims made in the labelling of a food must be explained and justified on the label and be capable of substantiation.
- There is no specific legislation on health claims other than the general provision that they must not be misleading or falsely describe a product.
- For many years, CEG has called for greater control over the use of claims made about foodstuffs. The number and range of these claims has grown in a way that has left consumers increasingly confused and without enough information to assess the claims objectively. Current legislation is inadequate to deal with the variety of claims now made about food and to ensure satisfactory enforcement of those claims. Surveys have shown that consumers are confused about the controls of claims on dietary supplements in particular, because these products often have the appearance of medicines but do not have to comply with strict regulations of medicines.
- CEG would prefer all health claims to be prohibited because they can so easily mislead consumers. They believe that claims should be limited to information on the objective, measurable aspects of a food that could enable consumers to make up their own minds about the health value of a food. Health claims are hard to justify for individual foods when the needs of individual consumers vary greatly and when diet and lifestyle factors are of key importance to health. The potentially useful educational role of health claims could be heavily outweighed by their potential to confuse and mislead consumers, who are not generally well informed about their individual health status. Ideally, consumers should be encouraged to achieve dietary change by the provision of clear, simple, accurate and comprehensive information and education about nutrition - not through marketing claims.
- CEG would prefer all health claims to be banned. However, if a political decision is made to allow them then this must be under very limited and strictly controlled conditions.

If health claims are allowed:

- CEG considers that health claims should be regulated at EU level to ensure consistency across the Single Market. In the absence of EU legislation, clear and detailed voluntary guidelines, such as the Code of Practice drafted by the JHCI, might provide a basis for control.
- Dietary supplements should be considered as foods for marketing purposes; clear criteria are needed to clarify the difference between foods and medicines.
- Health claims must be fully substantiated by scientific evidence that must be assessed by an independent expert body. CEG strongly supports the pre-market approval of health claims.
- CEG accepts that it could be useful to have a list of officially endorsed and acceptable health claims that are linked to nutrient function and that command a general scientific consensus.
- Any system for the approval of health claims must be transparent, credible, accountable and enforceable.

The Food and Drink Federation (FDF) does not believe that there are significant barriers to trade as a result of the regulation of health claims. However, they did

express concern that barriers to trade could arise as a result of the differing interpretation so of Directive 79/112. The FDF would like to see disease risk reduction claims allowed and points out that Directive 65/65 is no longer appropriate bearing in mind developments made in food production.

The FDF welcomes the JHCI and has been closely involved in its establishment and points out that failure to specify a particular disease on a claim can in itself be misleading. The FDF would welcome the JHCI as the only layer of regulation. However, the FDF is aware that the nature of the European Market will mean that a European solution to regulation will be necessary.

The FDF believes that claims should be an issue of consumer education not consumer safety but agree that the burden of proof should be on the maker of a claim to justify it. They also support voluntary systems for pre-marketing approval for claims.

3. Ethical Claims

The absence of legislation on ethical claims does not seem to have spurred any problems in terms of barriers to trade. However, according to the Fairtrade Foundation there is growing danger that consumers are being misled by the use of ethical claims. This is dealt with further in the section on voluntary instruments.

III. VOLUNTARY INSTRUMENTS USED

Please note that this section should be read in conjunction with the codes developed for the various means of communications, which are dealt with separately under Section VII.

A. VOLUNTARY INSTRUMENTS IN PLACE

1. Nutritional Claims

a. Food Advisory Committee

The rules provided in the Food Labelling Regulations 1996 are supplemented by guidelines based on recommendations made by the Food Advisory Committee. The guidelines are advisory and have no legal effect.

The Food Advisory Committee is a non-statutory body comprising a chairman and fifteen members appointed for their personal expertise. It does not represent a particular interest. The Committee's main task is to review and prepare reports on all matters within its terms of reference (to advise Ministers on the exercise of power in the Food Safety Act 1990 and to assess the risk to humans of chemicals which are used in or on food)

The most recent guidelines have been notified to the European Commission and will be issued following the notification process. A copy of the guidelines is provided in annex V.

b. Co-operative Wholesale Society Guidelines

The Co-operative Wholesale Society (CWS) (the owners of the Co-op) has developed its own code of practice for the labelling of pre-packed foods. The code covers both nutritional and health claims (as well as other types of claims and labelling requirements). A copy of the code is provided in annex VI.

The code was develop in 1997 and is applied to all own label products. The code is complemented by the Co-op's honest labelling campaign. Under the campaign, consumers are encouraged to comment on the Co-op labelling policy through the use of free phone and freepost services.

When a consumer makes a complaint, the Co-op may react to the complaint and make appropriate changes to its labelling policy. When there is dispute between the Co-op and a consumer, the complaint will be referred to the Co-op's jury. The jury is made up of members of the Co-op (the Co-op is a membership organisation) who are selected on the basis of their interest in labelling policy. The jury will then consider the complaint. The Co-op is bound by the jury's decision.

The code only applies to pre-packed food and addresses labelling from a consumer perspective rather than from an industry viewpoint. The code complements the Food Labelling Regulations and the Food Advisory Committee Guidelines.

As regards nutrition claims the CWS makes the following remarks:

- There are only limited criteria for nutrient content claims in law; otherwise the regulation on claims relies on general labelling provisions that information should not mislead the consumer;
- The lack of detailed provisions has led to a situation where labellers make factually correct claims, which show their products in the best light. However, because different criteria have been used in different product sectors the potential for misleading the consumer arises.

The code provides for the following rules with regard to nutrition claims:

- Compliance with the FAC guidelines as well as the Food Labelling Regulations
- Claims that are not meaningful to the population at large should be considered misleading. For example, there is no protein deficiency in the UK thereby invalidating a high protein claim.
- Alternatively if a product meets the criteria for a reduced nutrient claim but the difference in the particular nutrient content maybe insignificant because the level in the food of comparison is itself relatively low.
- Certain negative claims can imply naturalness to the consumer and may therefore be potentially misleading and must not be used. Example of these include (1) a claim for a food that is free from "X" if all foods in the same category are free from "X" (2) statements or implications which give undue emphasis to the fact that a product is free from certain non-natural additives, when the product contains other non-natural additives (3) a claim that a food is "free from" one category of additive when a similar additive of another category, or an ingredient having a

broadly similar effect, is used. (4) a claim that a food is "free from" one category of additives when the product contains other additives.

- The code also lays down detailed rules for nutrient content claims. These are attached in annex VI.

2. Health Claims

b. Joint Health Claims Initiative

A copy of the JHCI code is provided in annex VII.

i. Background

The development of a regulatory framework for health claims in the UK has focused on a voluntary initiative that has brought together the majority of interested parties, The Joint Health Claim Initiative.

The JHCI was established in June 1997 as a joint venture between consumer organisations, enforcement authorities and industry bodies to establish a code of practice for the use of health claims on foods.

The JHCI was set up following discussions initiated by the Ministry for Agriculture, Food and Fisheries and guidelines drafted by the Food Advisory Committee on health claims in December 1996. As a result, of these initiatives the Food and Drink Federation, the National Food Alliance (which has subsequently been renamed Sustain) and the Local Authority Coordinating Body on Trading Standards (LACOTS) agreed to work on a voluntary code on health claims.

Other interested parties were invited to assist in drafting the code (a list of the organisations, which were involved in the initiative, is attached in annex VI).

ii. Code administration body

Although the code has been finalised, the code administration body is still to be finalised. The code administration body will consist of:

(a) A Council which will include an equal number of representatives of consumers, industry and enforcement authorities. The Council's role will be to monitor the implementation of the code.
(b) A secretariat. At the time of our discussions with interested parties it seemed likely that the secretariat would be given to Leatherhead Food RA.
(c) An expert authority, which will consist of experts in the field of food and health and would provide opinions to anyone requesting a view on the scientific validity of a health claim.

At this stage, it should be pointed out that a number of interested parties, in particular the consumer associations hoped that the administration of the code would eventually fall within the competence of the Food Standards Agency once it has been set up.

iii. Objectives

The objectives of the code are defined as the following:

(a) Protecting and promoting public health
(b) Providing accurate and responsible information relating to food to enable consumers to make informed choices
(c) Promoting fair trade and innovation in the food industry
(d) Promoting consistency in the use of health claims in the UK, Europe and internationally.

iv. Legal Status of the code

The code makes it clear that it is not legally binding but points out that " compliance with this code should assist companies to establish a defence of due diligence if prosecuted for making a health claim under the Food Safety Act and other applicable laws."

It further points out that "providing this code is followed in its entirety, including seeking pre-market advice at an early stage and acting, if necessary on the outcome, disputes should not arise over the legality or scientific justification of an innovative health claim."

Despite these statements, it is clear that following the code will not provide a guarantee that a prosecution under the Food Safety Act would not be brought by the enforcement authorities. This is reflected in the code that states "ultimately it will be for the courts to decide whether or not a health claim is made in accordance with the relevant provisions of existing legislation."

v. Scope

The code applies to the use of health claims in labelling, advertising and promotion of all food as marketed to the general public whether foods, drinks or food supplements.

However, the code does not apply to the safety assessments of foods, which are subject to the safety requirements of the Food Safety Act 1990 and also to novel foods if they are subject to the Novel Foods Regulations 1997.

vi. General principles for making a health claim

In summary, the code states that health claims should assists consumers to make informed choices and that they expect that health claims have been substantiated by independent experts prior to use.

The overriding principle of the code is that the likely consumer perception of the health claims is paramount. The factors used to determine a consumer perception include:

- The possibility of misleading the consumer through marketing imagery

- The use of associated pictures, logos, words, sounds, phrases, shape of packaging or the item itself.
- The manner in which the product is presented to the consumer, including literature, ingredients highlighted, the form of the product, its name, who is promoting it to which group of people and the media used.
- The direct, indirect or implied meaning of the heath claim.

The above factors where stressed by Consumer Associations and, in particular, by independent bodies working in the field of nutrition. They pointed out that health claims should only be directed at groups who would see an overall health benefit from purchasing the product. It was pointed out that by and large products for which health claims were made were relatively more expensive. Therefore, substituting other foods for a product on which a health claims is made would have an overall effect on diet.

vii. Legal and nutrition principles

The general principle is that health claims must be truthful and must not mislead, exaggerate or deceive either directly or by implication. The claim must also indicate to which if any specific group the claimed benefit refers.

Other principles include:

- Any reference to a specific disease or to disease in general terms should be avoided, as this is likely to imply that food will have a medicinal effect. It is also pointed out that medicinal claims are prohibited by law.
- However, it is deemed acceptable to refer to the maintenance of good health in general or specific organs of the body.
- It is also acceptable to refer to risk factors that may adversely affect good health.
- However, any such reference must make it clear that the overall benefit is within the context of a healthy diet.
- The claim must not encourage or condone excessive consumption or disparage good dietary practice.
- The benefit from the claim must be fulfilled by consumption as recommended by the company or on the label.
- The benefit from the health claim must be derived wholly from the food for which the claim is made and not rely on any benefit derived from consumption with other foods.
- Health claims must be communicated in such a way to assist consumer understanding of the basis of the claim.
- Companies should take care to ensure that any health claim does not mislead vulnerable sectors of the population.

viii. Labelling and other consumer information

When a health claim is made companies are advised to provide additional information to assist consumer's understanding of the significance of the health claim. This is not an absolute requirement but companies are advised to include the following:

(a) a full nutrition declaration
(b) a quantified serving size
(c) the target population and anyone who should avoid using the food
(d) a statement indicating the quantity and pattern of consumption likely to achieve a beneficial effect.
(e) A safe maximum intake
(f) Wherever a food component provides the basis for a health claim, a declaration of the amount of this functional ingredient in 100g and/or one serving of the food whichever is the most appropriate.

ix. Substantiation of health claims

All health claims must be capable of substantiation. The Code Administration Body will maintain an updated list of generic and approved innovative claims.

x. Generic Health claims

In the case of generic health claims no specific substantiation is required. Companies wishing to make a generic health claim may do so for complying foods. Complying food comprises or contains the ingredients in sufficient quantity to produce the effects claimed or falls within the category of foods to which the generic health claim applies.

Any company may use a generic health claim on complying food without further documentation.

The code administration body is responsible for developing a list of generic health claims for approval by the Expert authority. The list will be regularly reviewed and updated in the light of international scientific consensus and new evidence.

xi. Innovative health claims

Substantiation of innovative health claims is essential. Companies must show that the health claim is likely to be true and that the scientific evidence in support of the health claim outweighs opposing evidence. Pre-market advice is strongly recommended before making a new health claim.

xii. The aims of substantiation

When using health claims companies must be able to demonstrate the following:

- That the food will cause or contribute to a physiological benefit when consumed by the target population as part of their normal diet.
- The claimed benefit can be achieved by consuming a reasonable amount of the food
- The effect is maintained over a reasonable period of time
- Indicate the target group that can benefit from the food
- How the effect is brought about

xiii. Source and nature of scientific evidence

The health claim must be based on a review of all the available scientific evidence.

The conclusions of this review should be based on:

(a) The totality of evidence not just data, which support the health claim
(b) Human studies or evidence
(c) Studies which are the most methodologically sound available.

The conclusions of the review should be based on experimental studies in humans. Additional information could be expected from the following sources.

(a) Human studies, including epidemiological and clinical studies
(b) Animal studies
(c) Biochemical and cellular studies
(d) Any other relevant sources

Research should assess the effects of foods on the health status of human objects.

xiv. Documentation of claims

Any innovative health claim must be supported by documentation of the scientific evidence demonstrating the physiological effect, which is claimed. Companies making an innovative health claim must prepare documentation of scientific evidence. Companies are strongly advised to seek the advice of the Code Administration body and their Home Authority at an early stage prior to making an innovative health claim.

It is suggested that documentation should include:

- Scientific and lay summaries of the evidence that is the basis of the claim.
- Name and description of the food.
- Identification of the specific component or combinations of components for which the health claim is made.
- Details of the chemical analysis carried out.
- A statement of intended use.
- Appropriate warnings
- Any advice of the code administration body sought prior to making an innovative health claim.
- A copy of the product label and samples of health claims made in advertising and other promotions.
- Contact details of independent scientific experts to whom the full scientific evidence have been referred for review.

xv. Pre-market advice for innovative health claims

Companies are strongly encouraged to seek pre-market advice from the Code Administration body before using an innovative health claim. The exact procedures for seeking pre-market advice and timescales for delivery will be established by the Council.

Companies may request an independent review by the Council of the advice given by the Expert Authority.

Acting upon pre-market advice suggest the exercise of due diligence. The Courts may take this into account in the event of any legal challenge to the health claim under he Food Safety Act. Similarly the Independent Television Commission, the Advertising Standards Authority and the Radio Authority are encouraged to take this procedure into account when deciding if a breach of the ITC, CAP or RA codes has occurred.

Companies who have not sought pre-market advice for an innovative health claim have not necessarily failed to exercise due diligence.

xvi. Determination of legality of borderline health claims

In cases where doubts arise as to the legality of a health claim the Code Administration body will refer the proposed claim to LACOTS and the Medicines Control Agency (MCA) for determination of its legality.

LACOTS and the MCA will jointly assess such claims on a case by case basis.

xvii. Access to evidence, information on health claims and confidentiality

All information held by the Code Administration body is freely available except in the following cases:

- Where data on innovative health claims is submitted to the Code Administration body, if such data is commercially sensitive confidence must be fully respected.
- The Code Administration body will draw up further guidelines on confidentiality and commercial sensitivity.

xviii. Suspected breaches of the code

In the event that the Code Administration body is aware that a health claim is being made, which may breach the Code, the Code secretariat may complain to the relevant enforcement, regulatory or self-regulatory bodies. The Code secretariat may make public the details of the complaint.

The Code Administration Body may disclose details of an opinion to enforcement, regulatory or self-regulatory bodies.

xix. Co-operative Wholesale Society Guidelines

As noted above in Section III.A.1, the CWS has a code of practice for labelling prepacked foods, which include guidelines on health claims.

The CWS makes the following remarks about health claims:

- There is no specific legislation setting criteria for medicinal and health claims.
- The only constraints on claims are the general provision that they must not be misleading or falsely describe a product.
- Modern technology increasingly allows foods to be manipulated to deliver health benefits. The absolute ban on referring to diseases prohibits effective consumer communication by, at best, forcing labellers to adopt less direct messages, at variance with generally accepted health messages and failing to capitalise on the benefits of short, sharp messages often repeated. At worst, it discourages claims all together.

The code addresses these issues in the following manner:

- For generally accepted, well established links between nutrients and disease the code lays down a number of so-called medicinal claim which can be used, provided the associated conditions are met.
- For all other health claims the code sets out general criteria which any claim must meet and requires each such claim to be approved by an authoritative body through the submission of a dossier of the scientific evidence. Additional labelling requirement for such claim are also laid down.

The guidelines for health claims are follows:

- All health claims must be valid.
- A dossier of scientific evidence supporting the claim must be compiled. The dossier, together with an example of the product label, must be submitted to and approved by a designated body. The dossier must be available to the public and enforcement inspection and must be able to stand up to scientific, peer review.
- Health claims must be based on good evidence of a likelihood of need in the population or of a clear benefit either from reducing or increasing the intake of the particular substance.
- No claims must be made for substances where there is evidence that excess consumption can be harmful if this is achievable from readily available foodstuffs and supplements.
- Claims must only be made where the amount of the substance in a serving provides a significant contribution to the recommended daily intake.
- The claimed benefit must apply to the food as eaten and must not rely on any benefit from consuming the food with other foods.
- Health claims must only be made on products, which are no less “healthy” than their regular counterparts.
- Health claims must not encourage excessive consumption.
- Care should be taken not to mislead vulnerable sectors of the population (pregnant women, lactating mothers and children).
- Claims must be accompanied by an on-pack guideline of the recommended daily amount and must be substantiated by a statement on the pack of the amount in a serving.
- Contra indications must also be included in labelling statements

The code also provides the following guidelines on so-called medicinal claims:

- A claim that the consumption or reduced consumption of food, nutrient or substance contained in a food, as part of a total dietary pattern, may have an effect on a disease or health related claim should only be made where all the conditions for health claims are met. In addition, there must be scientific consensus; supported by the Chief Medical Officer, the Committee on Medical Aspects of Food Policy or a similarly independent and authoritative source that a relationship exists between the food and the health-related condition.
- The wording of the claim must be made within the context of a total dietary pattern and include (1) amount serving per day (2) contra-indications and (3) special dietary regimes on which the claim is dependant.
- The following claims may be made where specified conditions are met (see annex VI for the conditions under which the claims may be used). No other claims may be made:
    1. X contains calcium which may reduce the risk of osteoporosis later in life
    2. X contains soluble fibre which may reduce the risk of heart disease
    3. X is low fat and a source of fibre, which may reduce the risk of some types of cancer.
    4. X is low in total fat, which may reduce the risk of some cancers.
    5. X is low in salt, which may reduce the risk of high blood pressure.
    6. X is rich in folic acid, which may reduce a woman's risk of having a child with spina bifida or other neural tube defects.

3. Ethical Claims

In the UK, there are a number of organisations that are involved in ethical trading but relatively few who have specifically established voluntary codes on ethical claims.

For example, the Ethical Trading Initiative (ETI) promotes ethical trading but does not include specific mention of ethical claims in its codes. According to the UK government, ETI members are prohibited from using their membership of the ETI as an ethical claim. However, our discussions with interested parties have indicated that there is growing pressure for ETI members to be able to make such claims. A copy of the ETI code is attached in annex VIII.

The Fairtrade mark appears to be the exception to this in the UK and is one of the few examples of a voluntary agreement on ethical claims. The Fairtrade mark is administered by the Fairtrade Foundation. Further details of the Fairtrade mark are attached in the annex. IX.

The Fairtrade mark provides an independent mechanism for assisting disadvantaged producers of specific commodities in developing countries by defining criteria for eligible producers and for terms of trade, establishing a register of qualifying producers, and monitoring transactions so as to provide a guarantee to consumers that products bearing a Fairtrade Label meet the agreed criteria.

The criteria used for defining Fairtrade standards for suppliers of licensed products include:

- For workers: decent wages, adequate housing, minimum health and safety standards and environmental standards
- For small holders: a genuine democratic producer co-op, a fair price, credit terms and a long term trading commitment.

The price paid includes a premium to be used in consultation with workers or producers to benefit the community.

The Fairtrade Foundation has set up a licensing system for companies that wish to use the Fairtrade Mark. The Fairtrade Foundations grants the right to use the Fairtrade mark on or in relation to products subject to the licensee complying with the terms and agreement of the license.

The terms and conditions of the license specify how the licensee shall use the Fairtrade mark. This includes the licensee submitting all packaging and advertising materials using or referring to the mark for approval by the Foundation. The licensee is also prohibited from using other marks denoting ethical trading.

B. DEFINITIONS USED IN THE VOLUNTARY INSTRUMENTS

Please note that the CWS does not include any definitions in its code of practice.

1. Nutritional Claims

The following definitions are used in the Food Advisory Committee guidelines for the use of certain nutrition claims in food labelling and advertising.

"Nutrition claim means any statement, suggestion or implication in any labelling, presentation or advertising of a food that that food has particular nutrition properties, but does not include a reference to any quality or quantity of nutrient where such reference is required by law".

"Sugars means all monosaccharides and disaccharides but excludes polyols"

"Fat means total lipids including phospholipids"

"Saturates means fatty acids with double bond."

"Fibre is yet to be defined but we advise that fibre, for claims and nutritional labelling purposes, means dietary fibre defined as non starch polysaccharides. Claims relating to fibre should be based on this definition."

2. Health Claims

For the purposes of the JHCI Code, the following definitions are used:

"Health claim"

A direct, indirect or implied claim in food labelling, advertising and promotion that consumption of a food carries a specific health benefit or avoids a specific health detriment. This includes nutrient function claims describing the physiological role of the nutrients in growth, development and normal functions of the body (e.g. calcium aids in the development of strong teeth and bones) but does not include nutrient content claims (e.g. that a food is low in fat, has reduced cholesterol or high fibre content).

“Generic Health Claim”

A health claim based on well-established, generally accepted knowledge from evidence in the scientific literature and/or to recommendations from national or international public health bodies such as the Committee on the Medical Aspects of Food and Nutrition Policy (“COMA”), the US Food and Drug Administration (“FDA”) or the EU Scientific Committee for Foods (“SCF”).

“Innovative Health Claim”

A health claim other than a generic health claim based on scientific evidence applied to existing or new foods and substantiated in accordance with Paragraph 8 of this Code. When the body of evidence in the published scientific literature is such that the link between the nutrient/ingredient and the claimed effect is generally accepted, the claim meets the criteria identified in paragraph 3.2 and the claim will become generic.

"Medicinal claim" and "human disease"

A medicinal claim is a health claim, which states or implies that a food has the property of treating, preventing or curing human disease or makes any reference to such a property. "Human disease" means any injury, ailment or adverse condition, whether of body or mind.

“Target Population”

The full population, sub-sections of the population or vulnerable sub-groups of the population to which the health claim applies.

“Labelling”

Includes any words, particulars, trademark, brand name, pictorial matter or symbol relating to the food and/or appearing on the packaging. It also includes any document, notice, label, ring or collar accompanying the food.

“Advertising”

Includes any notice, circular, mailing, invoice, or other document destined to be seen by the public and any public announcement made orally or by any means of producing or transmitting light or sound by any medium including

TV, radio, telephone or computer, but not including any form of food labelling. "Advertisement" shall be likewise construed.

"Promotion"

Includes product promotions and any public relations materials used directly or in association with the food, including, for example, testimonials and press releases, either written or broadcast, or materials provided alongside the food where it is displayed for sale where these are clearly a part of the advertising for the food and directly related to the food. It also includes the activities and statements of company and sales representatives. Material exclusively aimed at health professionals is not included provided there is no intention to bring the content of such materials to the attention of the general public. Promotion does not include editorial, opinion or the reporting of statements or activities by independent third parties not connected with the companies.

3. Ethical claims

The Fairtrade Foundation uses the following definitions

"Fairtrade Criteria" means the standards and terms of trade for specific product categories agreed by all the National Initiatives affiliated to FLO, as applicable at the Commencement Date and as subsequently revised.

"Packaging" means all materials normally supplied as part of the Product and includes (among others) all containers, wrappers, labels, and transit packaging.

"Advertising & Promotional Materials" means all materials and statements produced by the Licensee in the course of marketing the products and includes (among others) leaflets, brochures, catalogues, press and broadcast advertising, press releases and information published via the internet.

C. EXISTING PROHIBITIONS, RESTRICTIONS AND EXEMPTIONS

1. Nutritional Claims

Food Advisory Committee Guidelines

The Food Advisory Committee guidelines for the use of certain nutrition claims in food labelling and advertising provide for the following criteria:

"Low: claims for fat saturates, sugar(s) and salt/sodium should conform to the conditions in the attached annex (see annex V). Claims for other nutrients are outwith these guidelines, but reference should be made to Schedule 6 part II of the Food Labelling Regulations for conditions for energy.

- Claims for foods naturally low in a nutrient should take the form of "a low X food".
- Information in the nutrition panel on sodium level should be accompanied by an equivalent salt figure.

- Since dietary cholesterol is not a major factor in coronary heart disease and there is a danger of confusion with blood cholesterol levels, low cholesterol claims should not be made."

"No Added: claims for sugar(s) and salt should conform to the conditions in the attached annex (see annex V). Claims for other nutrients are outwith these guidelines."

"X free/without: claims for fat, saturates, sugar(s), and salt/sodium should conform to the conditions in the attached Annex (see annex V). The Food Labelling Schedule 6 part II lays down conditions for cholesterol free claims. However, as far as "low" cholesterol is concerned, it is recommended that such claims are not made. Claims for other nutrients are outwith these guidelines.

- Since "X% fat free" claims may be misunderstood, these should be avoided.
- Information in the nutrition panel on sodium levels should be accompanied by an equivalent salt figure."

"Source: claims for fibre should conform to the conditions in the attached annex (see annex V). Claims for other nutrients are outwith these guidelines, but reference should be made to the Food Labelling Regulations for conditions for protein, vitamins and minerals."

"Increased: claims for fibre should conform to the conditions in the attached annex (see annex V). Claims for other nutrients should only be made when there is a minimum 25% increase of the nutrient contained in the food by comparison with the normal product, i.e. the standard version of the product, for which no claim is made.

"Reduced: claims should only be made when there is a minimum 25% reduction of the nutrient contained in the food by comparison with the normal product, i.e. the standard version of the product, for which no claim is made. Reference should also be made to the Food Labelling Regulations Schedule 6 part II for conditions for energy and cholesterol. Again, it is recommended that cholesterol claims are not made."

"More/less: claims for food with changes in nutrient content of less that 25% should take the form "contains Y% less/more X".

"High/rich: claims for fibre should conform to the conditions in the attached annex (see annex V). Claims for other nutrients are outwith these guidelines, but see the Food Labelling Regulations Schedule 6 part II for condition for protein, vitamins and minerals. Claims for foods naturally high in a nutrient should take the form "a high X food".

Co-operative Wholesale Society code of practice

The code defines certain type of claims, which by their very nature will be considered misleading and are therefore prohibited.

They include the following:

- Clams that are not meaningful to the population at large or to a defined group of individuals e.g. vegetarians.
- A claim which is factually correct but which is insignificant either to the population or to the individual product (i.e. high protein claims in the UK – because there is no protein deficiency in the UK). Alternatively, a claim that implies that a product is in some way different when in reality all products of that type are the same.

2. Health Claims

Under the JHCI code, annex 1 (see annex VII) sets out the limits between what is considered to be a health claim and a medicinal claim and treats the issue of borderline cases. The code therefore provides guidance on how a legally acceptable claim may be made for a food, which has a role in reducing risk of disease.

Medicinal claims

The code points out that there is a general prohibition for medicinal claims for food products. If a food is intended for a medicinal purpose the making of a claim will need to be approved by the Medicines Control Agency through the granting of a product license. Supplying such a product without a medicine license is a criminal offence.

Use of certain word and phrases in health claims for foods

The code states that the following could give rise to the impression that a product can prevent, treat or cure disease (with the implication that this would be a medicinal claim and therefore prohibited under law but not necessarily under the code):

- Pictorial or other references to changes in the human body caused by disease.
- References to a specific disease.
- Non-specific references to disease in general.
- References to relief of "symptoms"
- Descriptions of particular symptoms which are perceived as signs of a disease (e.g. stress, anxiety, aches and pains, tension etc.)
- Targeting of products to sections of the population suffering from diseases or known to be at risk.
- Use of, or reference to, associated promotions or literature, which includes mentions of disease.
- References to a body function which is associated with the development of disease (such as cholesterol synthesis, formation of fat or body metabolism, immunity from infection etc.) unless the reference only relates to the continuation of its normal healthy function.
- The use of medical terminology and/or images to increase the association of the product with medical usage.

- The use of certain words and phrases which may not, taken alone, signify that a product can treat, prevent or cure human disease but may, if presented in a medical context, imply that the product can provide a medicinal benefit. Such words include:
  "restore, repair, eliminate, control, counteract, combat, clear, stop, alleviate, remove, heal, remedy, avoid, protect, relieve, regenerate, normalise, strengthen, check, end, fight, calm, detoxify, reduce or lower".

The code also gives examples of acceptable words and phrases in health claims and words and phrases that are unlikely to imply treatment, prevention or cure of disease.

Co-operative Wholesale Society code of practice

The following type of health claim are not allowed under the code:

- It is not appropriate to make a claim related to the function of a particular substance which, whilst true, could imply a health benefit from additional or reduced intake which could not be justified;
- No health claim can be made for products where there is evidence that excess consumption can be harmful, if this is easily achievable from readily available foodstuff and supplements.
- Health claims must only be made on products, which are no less "healthy" than their regular counterparts.

3. Ethical Claims

The Fairtrade Foundation Fairtrade mark can only be used subject to a contractual agreement between the Fairtrade Foundation and the licensee. The contractual agreement defines how the Fairtrade mark can be used.

If packaging or advertising materials are produced without the prior authorization of the Fairtrade Foundation and breach the conditions for the use of the Mark, the Foundation may require packaging to be reprinted and replaced within three months or materials to be withdrawn from circulation immediately.

The licensee is also contractually obliged to observe any other reasonable directions given by the Fairtrade Foundation as to the colouring, size, manner and disposition of the Mark on packaging and on advertising and promotional materials.

D. VOLUNTARY INSTRUMENTS ACCEPTED/RECOGNISED BY THE AUTHORITIES

Although the CWS code does not have any official recognition from the authorities, the CWS states that the Department of Health is thinking of using its code as the basis for further work in this area once the Food Standards Agency has been set up.

1. Nutritional Claims

The Food Advisory Committee's guidelines are advisory and have no legal effect. However, the government hopes that manufacturers will follow the recommendations

so as to ensure that consumers are given information in a helpful and consistent manner.

2. Health Claims

The UK government has indicated that it supports the JHCI, although it has not yet received ministerial approval. Notwithstanding, the government's position remains that it wishes to see EU level legislation on health claims.

It should also be noted that the European Commission has asked the UK government to notify the JHCI (see section on barriers to trade below).

In practice, the involvement of the enforcement authorities in the JHCI will give the initiative a form of official backing. The enforcement authorities are represented by the Local Authorities Coordinating Body on Trading Standards (LACOTS). LACOTS has been closely involved in the drafting of the code and will provide representatives for the JHCI Council. However, despite the involvement of LACOTS, it will remain up to individual local authorities, which are responsible for enforcing relevant legislation to decide whether to prosecute on a case by case basis. In practical terms, it should be noted that LACOTS welcomes the JHCI because it will remove an element of subjectivity from enforcement through the establishment of a list of generic health claims. LACOTS will advise Local Authorities to use the JHCI as guidelines for their activities. They also hope that the Code Administration Body will in effect be a substitute for court proceedings, which would only need to be used as a last resort.

3. Ethical Claims

The Fairtrade Foundation does not have any official recognition from the authorities.

In contrast, the Ethical Trading Initiative outlined above does have official government backing and has been set up with government financial support (approx. EUR 843 750 over three years).

E. REMARKS ABOUT BARRIERS TO TRADE AND LACK OF CONSUMER PROTECTION

The CWS code is subject to a system of complaints from consumers. Through the CWS's honest labelling campaign, consumers are encouraged to comment on claims. A complaint may result in the CWS changing its policy on claims. Where there is a dispute, the complaint is referred to a membership jury, which will adjudicate. The CWS is bound by the jury's decision. A copy of the Consumer Jury Complaints and Adjudication Procedure is provided in Annex X.

As the code of practice only applies to own-label products, it is unlikely to give rise to barriers to trade, except in so far as suppliers from outside the United Kingdom may be required to provide the Co-op with product information that would not be necessary with other suppliers.

1. Nutritional Claims

The Food Advisory Committee guidelines are notified to the European Commission in accordance with the provision of Directive 83/189. We understand that the UK government has notified the guidelines and will officially publish the guidelines shortly. The Commission and the other Member Sates have, therefore, the opportunity to bring to the UK government's attention any potential barriers to trade that may arise from the guidelines.

Concerns about consumer protection are referred to in Section II.F.1

2. Health Claims

One of the objectives in the JHCI is "promoting consistency in the use of health claims in the UK, Europe and internationally". The JHCI code has had to be notified to the European Commission under the Directive 83/189 on national rules affecting the free movement of goods. This will provide both the Commission and other Member States an opportunity to indicate whether they believe that the code will result in barriers to trade.

From our discussions, it appeared more likely that barriers to trade would arise from claims that are approved under the code in the UK but forbidden elsewhere in Europe. There was a general view that mutual recognition of a code would prove difficult and the authorities also pointed out that claims from outside the UK would not fall under the code.

Concerns about consumer protection are referred to in Section II. F. 2.

3. Ethical Claims

Under the contract with the Fairtrade Foundation, the licensee is only allowed to market its product primarily in the UK and may not actively market its products in those countries that have their own Fairtrade Labelling Organisations International (FLO) affiliated Fairtrade Labelling Initiative. That is unless a separate license agreement is entered into with the appropriate Fairtrade Labelling Initiative.

This provision might give rise to concern to barriers to trade in the Internal Market. However, we understand that the Fairtrade Foundation and its sister organisations are moving towards international definitions and consistency. This is being co-ordinated by the FLO.

The Fairtrade Foundation is aware of the difficulties that exist for consumer protection in ethical claims. This arises from the fact that anyone is free to make an ethical claim. There is no agreed definition of an ethical claim. It was suggested that ethical claims could include the following: animal welfare claims, social standards/employment claims, fairtrade social/marketing claims, or simply claims by companies that they are acting ethically. This can lead to confusion for the consumer. An example was cited where two different fairtrade labels could both claim that a minimum price was guaranteed for a producer of a certain product i.e. coffee. However, because the guaranteed price is different the consumer may chose to buy the cheaper product even though the guaranteed price for the producer may be lower.

This can generate competition between ethical claims. As a solution it was proposed that the emphasis should not be on a definition of a claim but agreeing standards for certification/justification of ethical claims/fairtrade.

The example mentioned above by Fairtrade Foundation raises important questions relating to consumer protection. The lack of definition of claims and the ability of manufacturers of products to place their own claims on products could lead to consumers being misled. The lack of any system of control leaves the market for ethical claims wide open to abuse.

IV. VERIFICATION SYSTEMS

A. CRITERIA FOR SUBSTANTIATING CLAIMS

1. Nutritional Claims

According to the UK government, UK law does not provide an inventory of criteria for substantiating nutrition claims. It is up to the courts to decide whether or not a particular claim contravenes the law. Responsibility for enforcing the law is with the local authorities.

2. Health Claims

According to the UK government, UK law does not provide an inventory of criteria for substantiating nutrition claims. It is up to the courts to decide whether or not a particular claim contravenes the law. Responsibility for enforcing the law falls to the local authorities.

The JHCI code does, however, include a section on the substantiation of Health claims. This is discussed in further detail in Section III. A. 2.

3. Ethical Claims

No legal provisions exist for the verification of ethical claims under UK law. However, the Fairtrade Foundation has a list of criteria that a manufacturer must meet in order to qualify for the Fairtrade Mark. These are referred to as the Fairtrade Criteria, which mean the standards and terms of trade for a specific product categories agreed by all the National Initiative's affiliated to the FLO. The criteria are developed for each type of product for which the Fairtrade Mark can be used. Criteria are applied to both the importers/packers of the product as well as to "accepted sources" of the product. A full list of the "tea" criteria is provided in annex XI.

B. LEGAL/ADMINISTRATIVE SYSTEMS FOR VERIFYING CLAIMS

The system for verifying claims under the Co-operative Wholesale Society code is dealt with in Section V. E.

1. Pre-Clearance Rules/ Guidelines

A wide variety of pre-clearance rules exist in the UK and these are found in the various self-regulatory initiatives.

The JHCI encourages manufacturers to seek pre-clearance of health claims and, in particular, innovative health claims. Companies wishing to do so can submit substantiating evidence to the Code Administration Body for advice from the Expert Authority. The exact procedures for seeking pre-market advice and timescales for its delivery have yet to be established by the Council.

Further details of the pre-clearance rules are provided in Section III.A.2.

All the bodies that administer the means of communication encourage pre-clearance for all types of claims. In some instances, such as for Radio broadcasts, health claims must be submitted for pre-clearance. In other instances, for example, television broadcasting this is the normal procedure as the costs involved in producing television commercials are such that pre-clearance advice is almost always sought.

However, it must be noted that none of the pre-clearance systems provide the manufacturer with a guarantee that their particular claim will comply with the respective codes or the law.

In the case of the media, the pre-clearance advice is given by either the Broadcasting Advice Clearance Centre (BACC) or the Radio Advertising Clearance Centre (RACC) or in the case of the non-broadcast media the Committee on Advertising Practice (CAP).

The role of these bodies is dealt with separately under Section VI.

2. Post-Clearance Rules/Guidelines

Control of Misleading Advertising Regulations

Under the Control of Misleading Advertisements the following rules apply.

The Director-General of the Office of Fair Trading has the power to stop an advertisement by means of a court injunction. The Director-General's powers only apply to the following types of advertisement:

- Newspapers and magazines;
- Outdoor advertising including bus, taxi and aerial advertisement, as well as posters;
- Cinema commercials;
- Brochures, leaflets, inserts, point of sale advertising, display materials, circulars and direct mail.

The Director-General's powers come into play when a complaint about an advertisement is made to him. However, before he considers the complaint he can ask the complainant to show that the existing channels have been given a reasonable opportunity to deal with the problem.

The main existing channels are:

- Trading Standards Departments who enforce the Trade Descriptions Act.
- The Advertising Standards Authority which administers the British Codes of Advertising and Sales Promotion.

The Director-General can only act when a complaint has been received. The complaint must be about the misleading nature of the advertisement, which is defined in the regulations as:

"for the purposes of these regulations an advertisement is misleading if in any way, including it presentation, it deceives or is likely to deceive the persons to whom it is addressed or whom it reaches and if, by reason of its deceptive nature, it is likely to affect their economic behaviour or, for those reasons, injures or is likely to injure a competitor of the person whose interest the advertisement seeks to promote."

An advertisement can be deceptive in various ways including where, for example, it:

- Contains a false statement of fact – this may be possible to prove or disprove by evidence;
- Conceals or leaves out important facts;
- Promises to do something but there is no intention of carrying it out;
- Creates a false impression, even if everything stated in it may be literally true.

If having considered the advertisement, the Director-General thinks it is misleading, then he has to decide whether to take court action. In making this decision he must have regard to all the interests involved, particularly the public interest. This means he will assess the gravity of the complaint. The factors for assessing the gravity of the complaint include:

- Health and safety
- The nature of the goods or service advertised
- Loss suffered by the complainant
- The nature of the target audience
- The likely size of the target audience
- The cost of products or services advertised.
- The need for speed in seeking a ban on the advertisement.
- The likely hood of continued publication if court proceedings are not started

The Director-General will take court action where he considers it warranted by the gravity of the misleading advertising and no immediate undertaking is given to amend or discontinue it. He will seek a High Court injunction.

3. What are the administrative/legal costs

There are no specific legal and administrative costs for those who wish to make a complaint.

C. LEGAL PERSONS ENTITLED TO TAKE LEGAL ACTION

Food Safety Act 1990

Section 6 of the Food Safety provides the following:

(1) In this act "the enforcement authority", in relation to any provision of this Act or any regulations or orders made under it, means the authority by whom they are to be enforced and executed.

(2) Every Food authority shall enforce and execute, within their area, the provisions of this act with respect to which the duty is not imposed expressly or by necessary implication on some other authority.

Section 5 of the Act defines the food authorities as "each London borough, district or non-metropolitan county, the council of that borough, district or county" (hereafter referred to as local authorities).

Control of Misleading Advertising Regulations

Any person may complain to the Director-General of the Office of Fair Trading under the Control of Misleading Advertising Regulations. Only the Director-General may seek an injunction.

Food Labelling Regulations 1996

Section 45 of the Food labelling Regulations 1996 provides the following:

"each food authority shall enforce and execute these regulations in its area"

Trade Descriptions Act 1968

Article 26 of the Trade Descriptions Act provides that Trading Standards (or Consumer Protection) Departments are responsible for enforcing the act. The Departments are part of the respective local authorities.

D. BURDEN OF PROOF

1. Burden of proof

Control of Misleading Advertising Regulations

The burden of proof is on the Director-General of the Office of Fair Trading to prove that the advertisement is misleading.

The Food Labelling Regulations 1996

The burden of proof is on the enforcement authorities to show that an offence has occurred under the regulations.

In the case of a claim this is provided under section 44(b) that provides:

"if any person sells or advertises for sale any food in respect of which a claims is made, nutrition labelling is given or a description or name is used in contravention of the provision of part III of these regulations".

Food Safety Act 1990

The burden of proof is on the enforcement authorities to show that an offence has been committed.

In the case of claims this is provided under section 15 that provides:

"Any person who gives with any food sold by him, or displays with any food offered or exposed by him for sale or in his possession for the purpose of sale, a label, whether or not attached to or printed on the wrapper or container, which,

(a) falsely describes the food; or
(b) is likely to mislead a to the nature or substance or quality of the food

shall be guilty of an offence."

E. APPLICABLE PENALTIES

Control of Misleading Advertising Regulations

There are no specific penalties under the Control Misleading Advertising Regulations except in that the Director-General of the Office of Fair Trading can seek an injunction to stop the advertisement.

Food Safety Act 1990

Section 35 provides:

"(2) A person found guilty of any other offence under this act shall be liable -

(a) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or to both".
(b) on summary conviction, to a fine not exceeding the relevant amount or to imprisonment for a term not exceeding six months or to both."

(3) In subsection (2) above the relevant amount means –
  (a) in the case of an offence under section 7,8, or 14 above £20 000 (EUR 31 250);
  (b) in any other case, the statutory maximum."

Note the relevant section for claims is section 15.

Food Labelling Regulations 1996

Section 44 of Food Labelling Regulations provides that if any persons commits an offence "he shall be liable on summary conviction to a fine not exceeding level 5 on the standard scale £5000 (approx. EUR 7812) ."

Trade Descriptions Act 1968

Section 18 provides:

"a person guilty of an offence under this act for which no other penalty is specified shall be liable –

(a) on summary conviction, to a fine not exceeding £400 (approx. EUR 625). This figure has been raised to £ 5000 (approx. EUR 7812); and
(b) on conviction or indictment to a fine or imprisonment for a term not exceeding two years or both.

F. REMARKS ABOUT BARRIERS TO TRADE AND LACK OF CONSUMER PROTECTION

As is demonstrated above, the legislative measures in place in the UK all require the enforcement authorities to prove that any particular claim that is being made is contrary to the provisions of the various rules in force.

In the case of the Trade Descriptions Act, the Food Labelling Regulations and the Food Safety Act the offences are criminal offences and therefore the burden of proof is "beyond reasonable doubt". In the case of the Control of Misleading Advertising Regulations, the Director-General would need to show that on the "balance of probabilities" that a claim is misleading.

This has repercussions for the decision by the enforcement authorities to take action against makers of claims, in particular where there is contradictory scientific evidence on a specific claim.

V. CASE LAW

There is a limited amount of case law available on claims in the UK. The reasons for this appear to be threefold:

- The UK system of regulation is heavily based on self-regulation and, therefore, disputes tend to be resolved outside the legal system. This is particularly the case with regard to the regulation of the means of communication.
- Even where there are specific legislative provisions on claims, the system is such that the parties are encouraged to reach an agreement outside the courts.
- The authorities responsible for the enforcement of legislation are the local authorities. There is reluctance on the part of the local authorities to bring cases before the courts. This is due to a number of reasons but the most important

appears to be cost and the difficulties in securing a judgement as a result of the burden of proof being on the plaintiff to show that the claim is not justified.

In addition to the case law on health claims, the Medicines Control Agency in closely involved in regulating borderline cases. Examples of these are set out below.

1. Nutritional Claims

No cases involving nutritional claims were mentioned to us.

2. Health Claims

Two cases have been drawn to our attention.

1. Cheshire County Council versus Mornflake Oats

In this case, the defendant used the claim that its product helped to "reduce excess cholesterol levels, cutting down the risk of heart disease".

The Divisional Court ruled that this was a medicinal claim, which could not be made unless a product license has been issued under the Medicine Act 1968.

The Court concluded that:

- The claim had the inevitable result that the disease would be prevented by being eliminated altogether; and
- The words cutting down had no meaning at all, unless those persons suffering from the disease would suffer to a less acute degree than they otherwise would have done.

2. In this case the defendant used a claim on a product suggesting that it would raise a child's IQ. The plaintiff was Shropshire County Council and the Court ruled that the claim had not being justified and that the claim was unlawful under the Trade Descriptions Act.

3. Ethical Claims

No cases involving ethical claims were mentioned to us.

4. Borderline cases

The example given the MCA of a borderline case is the PrevaCan case. The MCA took the view that the name of the product and the marketing strategy amounted to the presentation of it "for treating or preventing disease". Copies of the some of the marketing material are attached in Annex XII.

The MCA took the view that the claims were medicinal and where therefore in breach of medicinal and food legislation. However, as the product was a food it was up to the Food Regulators to take action. Nevertheless, the food regulators resisted and the MCA decided to take its own legal advice. The advice was supportive the MCA right

to take action but pessimistic about the potential outcome of the case. The MCA was advised to continue discussions with the manufacturers alongside the Food regulator. The manufacturer has since suggested changing the name and promotional material. This is also included in Annex XII.

B. REMARKS ABOUT BARRIERS TO TRADE AND LACK OF CONSUMER PROTECTION

There is considerable evidence to suggest that the lack of resources available to local authorities results in a number of claims being made that would otherwise be unlawful. We are not in a position to judge whether this has the direct effect of a lack of consumer protection.

LACOTS has provided us with a summary of a study carried out by local authorities in Wales that assess whether claims comply inter alia with the Food Labelling Regulations 1996.

This study would seem to imply that a number of claims are being made that in the judgement of the local authorities are unlawful. The summary of this study is provided in annex XIII.

However, the local authorities are not in a position to systematically enforce relevant legislation

VI. MEANS OF COMMUNICATION

The UK has a sophisticated mix of regulatory and self-regulatory systems in place for the control of claims/advertising in the different forms of media. These are dealt with here under two categories (broadcast (radio and television) and non-broadcast).

A. BROADCAST

The broadcast sector is regulated by a system of statutory bodies (the Independent Television Commission and the Radio Authority) and a system of pre-clearance advice given by the Broadcast Advertising Clearance Centre (BACC) and the Radio Advertising Clearance Centre (RACC).

1. Television

The Broadcasting Act 1990 makes it the statutory duty of the Independent Television Commission (ITC) to draw up and enforce a code governing standards and practice in television advertising and the sponsoring of programmes. A copy of the code is provided in annex XIV.

All holders of relevant ITC licenses are required to ensure that any advertising they transmit complies with the Code and to satisfy the ITC that they have adequate procedures to fulfil this requirement. The ITC itself draws up the Code and revises the rules, advises broadcasters on interpretation, monitors compliance and investigates complaints. The ITC has statutory powers to enable advertisements to be withdrawn

from air if they are deemed to be in contravention of the Code. They may also, in appropriate cases, impose penalties on the broadcasters, including financial penalties and in extreme cases, the curtailment and eventual rescinding of a broadcaster's license.

2. ITC Code

The ITC code provides the following in respect of health claims:

"Subject to the generality of the code, health claims and the advertising of medicines, treatments and dietary supplements are subject to more detailed rules in Appendix 3."

The majority of the Appendix deals with advertising of medicinal products rather that health claims in particular. However, section 36 deals with health and nutrition claims as follows:

"(d) specific nutrition claims (e.g. "full of the goodness of vitamin C) or health claims (e.g. aids a healthy digestion) must be supported by sound scientific evidence and must not give a misleading impression of the nutritional or health benefits of the food as a whole. More generalized claims or descriptions which imply nutritional or health benefits (e.g. "wholesome") without stating the basis for which them explicitly in the advertising are acceptable only if there is in fact a specific basis for them which is similarly supported by sound scientific evidence. Such claims will, where relevant be assessed by reference to the concept of a balanced diet."

In addition, the following general notes are provided

(i) Particular attention should also be paid to the requirements of the Food Labelling Regulations 1996, especially the prohibited and restricted claims set out in Schedule 6. Licensees and advertisers are advised to bear in mind that it is illegal to make medicinal claims on behalf of food products unless the product has a product license under the Medicines Act."

In order to comply with the code, broadcasters have established a body to assist with pre-clearance of television advertising. The Broadcast Advertising Clearance Centre's (BACC) role is to examine advertisements before they are accepted for broadcasting, to decide whether they comply with the relevant code and to handle day-to-day negotiations with the advertising agencies and advertisers.

3. BACC guidance notes

The BACC has developed its own guidance notes, which are intended to be read in conjunction with the ITC code, whose rules they supplement and expand. A copy of the guidance notes is provided in Annex XV. Section 5 is dedicated to Medicines, Treatments and Health Claims.

Section 4.5 states the following:

"Claims that goods are healthy must be made with proper regard for the interpretation likely to be placed upon the word by the lay person. Foods may be described as

"healthy" or "nutritious" only if BACC's medical consultants are satisfied that they are demonstrably capable of playing a significant role in a well balanced diet". The word healthy is not acceptable if used merely as a loose synonym for "wholesome".

Similarly terms such as "goodness" need to be used with discretion, to avoid exaggerating a food's contribution to the diet. "Goodness" is not acceptable simply as a synonym for "wholesomeness".

Most foods are wholesome and many are nutritious. However, the fact that a food product may be a good source of nutrients which, in isolation, are important or even essential for good health is not of itself a sufficient justification for promoting that product on a platform of general nutritional benefit. Claims in this area need to be assessed having regard to the likely dietary requirements of the UK population in general.

For example, although fat is essential to the well being of the human metabolism, most available evidence suggests that the majority of British people would be well advised to reduce the amount of fat in their diet. In these circumstances, it would be inappropriate to advertise a fat-rich product on the basis of a claim, express or implied, that it was "good for you", nutritious, or that it had a part to play in a "healthy diet", even though these statements might be perfectly justifiable in absolute scientific terms.

The acceptability of claims about a product's nutritional benefits will be assessed on this basis, with the advice, where necessary of BACC's medical and nutritional advisors.

In some foods, the presence of a nutrient for which a claim of nutritional benefit can be justified is offset by another, less desirable ingredient. In such cases, the acceptability of a positive nutritional claim for the product as a whole will depend on the extent to which the presence of the "negative" ingredient detracts from the benefit offered by the "positive" one.

In certain circumstances it may be acceptable for a food product unable to claim in absolute terms to be "healthy" or" good for you", for example because of its fat, salt, or sugar content, to make a justifiable claim to be "healthier" or "better for you" because it contains significantly less of those ingredients than are commonly to be found in such foods, so that its substitution for them would produce a positive benefit."

Inter alia, the BACC's code also includes sections on general food law, ingredient and additives, creative treatments and descriptions, and dietary aids to slimming.

According to the ITC and the BACC, 90% of all broadcast advertisements receive pre-clearance from the BACC.

However it should be pointed out that the ITC has no direct link with the advertiser. The only link is with the broadcaster.

4. Radio

A similar structure exists for radio. The Statutory body is the Radio Authority (RA) which licenses and regulates commercial radio in accordance with the Broadcasting Act 1990 and the Broadcasting Act 1996. The RA has approved the Radio Advertising Clearance Centre (RACC) as responsible for clearance of radio advertising.

5. RA Code

The Radio Authority has developed a code on advertising and sponsorship. A copy of the code is provided in Annex XVI. The RA code provides that certain special categories of advertising must be approved by the central clearance authority. These special categories include food and nutrition claims. Therefore, any advertisement, which includes a food and nutrition claim, must be approved by the RACC.

The RA code on advertising and sponsorship includes a section devoted to medicines, treatments and health, which provides that "health claims and the advertising of medicines and treatments (including veterinary products) are subject to the rules at Appendix 4.

Inter alia Appendix 4 provides the following:

"Claims about any type of product or treatment which fall within this Appendix require very close scrutiny. Whenever a proper assessment of such claims can only be made by a medically qualified expert, appropriate independent medical advice should be sought before acceptance. This includes claims relating to the nutritional, therapeutic or prophylactic effects of products such as food or toilet products."

The appendix also includes a specific section on generalized health claim for food, which provides:

"Generalised claims such as "goodness" or "wholesome" may imply that a food product or an ingredient has a greater nutritional or health benefit than is actually the case. In some instances, reference to the properties of a particular ingredient may give a misleading impression of the properties of the product taken as a whole. Such claims are unacceptable unless supported by sound medical evidence.

Particular attention should also be paid to the requirements of the Food Labelling Regulations especially the prohibited and restricted claims set out in Schedule 6."

6. RACC guidelines

The RACC guidelines provide that special categories of advertisements require clearance for the RACC. This list includes food and nutritional claims.

A copy of the Radio Advertising Clearance Centre Radio copy guidelines is provided in annex XVII.

B. NON-BROADCAST MEDIA

1. Advertising Standards Authority

The non-broadcast media in the UK is subject to a system of self-regulation that is administered by the Advertising Standards Authority (ASA). The ASA provides independent scrutiny of the self-regulatory system administered by the Committee on Advertising Practice (CAP). CAP is responsible for the British Codes of Advertising and Sales Promotion. A copy of the British Codes of Advertising and Sales Promotion is provided in annex XVIII.

Its chief tasks are to promote and enforce high standards in advertisements, to investigate complaints, to identify and resolve problems through its own research, to ensure that the system operates in the public interest and to act as a channel for communications with those who have an interest in advertising standards.

The ASA is an independent company and is independent of both the advertising industry and the government.

The ASA's complaint's system has the following steps:

(i) complaint received – ASA sends an acknowledgement card and assess the complaint
(ii) Decision – case needs investigating or complainant advised that there is no case to answer under the codes
(iii) Investigation – ASA asks the advertiser to comment on the complaint and supply evidence for any disputed claims
(iv) Considering the complaint – Advertisement assessed in the light of advertiser's response
(v) Decision – ASA Council adjudication
(vi) Taking Action – Advertiser and complainant notified of ruling. Where complaint is upheld, ASA asks for the advertisement to be amended or withdrawn
(vii) Publication of ruling – ASA publishes outcome of the investigation in the Monthly report which is circulated to journalists and the industry
(viii) Final check – ASA checks that the advertisement has been changed or withdrawn.

2. Committee on Advertising Practice (CAP)

The Committee on Advertising Practice is the self-regulatory body that devises and enforces the British Codes of Advertising and Sales Promotion.

CAP also administers the mandatory pre-clearance of cigarette advertising and provides free and confidential pre-publication advice to advertisers and promoters, their agencies, the media and produces Advice Notes and Ad Alerts for the industry and co-ordinates the sanctions operated by its members.

Favourable pre-publication advice does not automatically protect advertisers or promoters from their complaints being investigated by the ASA.

A list of all the Members of CAP is provided in annex XVIII.

3. British Codes of Advertising and Sales promotion

The British Codes of Advertising and Sales Promotion are drafted by the CAP.

In its broadest sense the code requires that advertisements and sales promotions should be:

- Legal decent, honest and truthful
- Prepared with a sense of responsibility to consumers and to society
- In line with the principles of fair competition and generally accepted in business.

The code also contains specific provisions on health and beauty products and therapies:

- Medical and scientific claims made about beauty and health-related products should be backed by trials, where appropriate conducted on people. Substantiation will be assessed by the ASA on the basis of established scientific knowledge.
- Advertisers should not discourage people from having essential treatment; medical advice is needed for serious or prolonged ailments and advertisers should not offer medicines or therapies for them.
- Advice, diagnosis or treatment of any serious medical condition should be conducted face-to-face. Advertisers inviting consumers to diagnose their own minor ailments should not make claims that might lead to a mistaken diagnosis.
- Consumers should not be encouraged to use products to excess and advertisers should not suggest that their products or therapies are guaranteed to work, are absolutely safe or without side effects for everyone.
- Advertisements should not suggest that any product is safe or effective merely because it is 'natural' or that it is generally safer because it omits an ingredient in common use.
- Advertisers offering individual treatments, particularly those that are physically invasive may be asked by the media and the ASA to provide full details together with information about those who will supervise and administer them. Where appropriate, practitioners should have relevant and recognised qualifications. Consumers should be encouraged to take independent medical advice before committing themselves to significant treatments.
- References to the relief of symptoms or the superficial signs of ageing are acceptable if they can be substantiated. Unqualified claims such as 'cure' and 'rejuvenation' are not generally acceptable.
- Claims made for the treatment of minor addictions and bad habits should make clear the vital role of willpower.
- Advertisers should not use unfamiliar scientific words for common conditions.
- Advertisers should hold scientific evidence for any claim that their vitamin or mineral product or food supplement is beneficial to health.
- A well-balanced diet should provide the vitamins and minerals needed each day by a normal, healthy individual. Advertisers may offer supplements as a safeguard, but should not suggest that there is widespread vitamin or mineral

deficiency or that it is necessary or therapeutic to augment a well-balanced diet. Advertisements should not imply that supplements will guard against deficiency, elevate mood or enhance performance. Supplements should not be promoted as a substitute for a healthy diet.

- Certain groups of people may benefit from vitamin and mineral supplementation. These include people who eat nutritionally inadequate meals, the elderly, children and adolescents, convalescents, athletes in training, those who are physically very active, women of child-bearing age, lactating and pregnant women and dieters. In assessing claims the ASA will bear in mind recommendations made by the Department of Health.
- Serious vitamin and mineral depletion caused by illness should be diagnosed and treated by a doctor. Self-medication should not be promoted on the basis that it will influence the speed or extent of recovery.

VII. STATISTICS ON CLAIMS

As discussed in section V.B LACOTS has provided us with a summary of a study carried out by local authorities in Wales that assess whether claims comply inter alia with the Food Labelling Regulations 1996.

This study would seem to imply that a number of claims are being made that in the judgement of the local authorities are unlawful. The summary of this study is provided in annex XIII.

Two other studies examining nutritional and health claims have been carried both by the Food Commission:

- "Functional Foods Examined: the health claims being made for food products and the need for regulation" by Jane Bradbury, Tim Lobstein and Vivien Lund, April 1996.

- "Food Supplement Claims: a survey of over 700 nutritional ad health claims being made by over 300 food supplements showing a need for clearer and stronger regulations to prevent consumers being misled" by Viv Stein, July 1997

Full copies of these studies are provided in annexes XIX and XX.

VIII. ANNEXES

I. Food Labelling Regulations 1996
II. Food Safety Act 1990
III. Trade Descriptions Act 1968
IV. Control of Misleading Advertising Regulations 1988
V. Food Advisory Committee Guidelines for the Use of Certain Nutrition Claims in Food Labelling and Advertising
VI. Co-operative Wholesale Society Code of Practice for labelling prepacked foods.

VII. Joint Health Claims Initiative Code of Practice on Health Claims on Foods
VIII. Ethical Trading Initiative, Purpose, principles programme membership information.
IX. The Fairtrade Foundation; Fairtrade Mark General Criteria
X. Co-operative Wholesale Society Consumer Jury Complaints and Adjudication Procedure
XI. Fairtrade Foundation, Tea Criteria of the International Producer Register – A viable alternative for disadvantaged producers.
XII. Prevacan promotional material
XIII. LACOTS Summary on Evaluation of Claims
XIV. The Independent Television Commission Code of Advertising Standards and Practice.
XV. Broadcast Advertising Clearance Centre, Guidance notes on pre-transmission clearance for Television Advertising.
XVI. Radio Authority Advertising and Sponsorship Code
XVII. Radio Adverting Clearance Centre radio copy guidelines.
XVIII. British Codes of Advertising and Sale Promotion
XIX. Functional Food Examined; the health claims being made for food products and the need for regulation.
XX. Food Supplement claims: a survey of over 700 nutritional and health claims being made by over 300 food supplements showing a need for clearer and stronger regulations to prevent consumers being misled.

IX. CONTACT DATABASE

Q. UNITED STATES

I. EXECUTIVE ANALYSIS

A. INTRODUCTION

This study was greeted with interest by regulatory authorities and other interested parties in the United States, where considerable experience has been gained in the regulatory treatment of nutritional and health claims. The study has been conducted at a time when the U.S. system governing nutritional and health claims has undergone substantial changes. These have had an important impact on the numbers of products making such claims, and the ability of regulators to effectively police and control them. These changes hold potentially important lessons for how this issue should be approached in the European Union (EU).

The following Executive Analysis outlines the main points of interest in relation to the U.S. system, the major changes it has undergone, and the principal consequences of these changes.

B. MEMBER STATE POLICY

1. Nutritional and health claims

The U.S. Government applies a comprehensive regulatory scheme to manufacturers making health and nutrition claims on labelling and in advertising of food and dietary supplement products. This regulatory scheme includes definitions of health and nutrition claims that are similar to those applied within the EU, and is in many areas very specific about the types of claims that can be made, the specific language that can be used, and even the prominence that the claim can be given in relation to other labelling information.

In general, these definitions are thought by most parties to distinguish fairly clearly between the claims that are permissible on food products, and those claims that would lead a product to be classified as a medicinal product or drug. However, recent government efforts to develop regulations drawing a clearer line between health claims and certain nutrition support statements (i.e., structure/function claims), especially for dietary supplements, have caused considerable confusion and concern, and are still being sorted out.

The U.S. regulatory approach is designed to strike a balance between the need to ensure a high level of consumer information and protection on the one hand, and the desire to allow the food and dietary supplement industries to develop to their full economic potential (and to use valid nutrition and health claims as part of their effort to do so) on the other.

Under the U.S. regulatory regime in the early 1990s, the terms upon which manufacturers could make nutrition or health claims were quite clear. Prior approval of the U.S. Food and Drug Administration (FDA) was generally required, and the

FDA issued very specific regulations on how that approval could be obtained. There was, therefore, an element of certainty in the marketplace as to which claims were permissible and which were not. Many consumer advocacy groups felt that the prior authorization system afforded a relatively high level of consumer protection. Many manufacturers, however, felt that the FDA approach to claims was far too restrictive.

Reforms adopted between 1994 and 1997 created alternative bases (other than prior FDA approval) on which manufacturers could make claims. In 1994, the U.S. Congress adopted legislation allowing dietary supplement manufacturers to make structure and function claims without prior government approval, a step which led to several thousand such claims being notified (as required) to the FDA. More recently, the U.S. Congress adopted legislation allowing nutrition and health claims to be made if they were based upon an authoritative statement (e.g., an official report) of one of the federal government's scientific bodies.

2. Ethical claims

There is no regulation in the United States on ethical claims. Moreover, only a very small amount of activity has taken place in this area.

C. VOLUNTARY CODES OF PRACTICE

1. Nutritional and health claims

Partly because of the pervasive nature of the U.S. regulatory regime, there is relatively little development on voluntary codes of practice that specifically relate to nutrition and health claims. Several related sectors have developed codes dealing with other aspects of industry standards, such as good manufacturing practices, but these generally do not contain comprehensive standards for claims that create a real alternative to the U.S. regulatory and enforcement regime.

2. Ethical Claims

The U.S. does not have a specific regulatory regime for the making of ethical claims, although there has been some activity relating to claims for environmental or social purposes. The Federal Trade Commission (FTC), for example, has adopted guidelines governing the use of environmental claims in product marketing, and was petitioned several years ago by consumer organizations to develop comparable guidelines governing the use of claims that products were manufactured without having been tested on animals. The FTC declined to take up this petition, however, and its officials indicate that they have not been pressed to adopt guidelines on social or other ethical claims. Some consumer groups believe that U.S. industry has effectively quashed any consideration by government of a regulatory scheme governing such claims.

D. VERIFICATION SYSTEMS

In addition to providing for pre-clearance as one means of making certain claims, the U.S. maintains what appears to be a vigorous enforcement scheme aimed at ensuring manufacturers' compliance with the relevant regulations. At federal level,

enforcement efforts are led by the FDA (for product labelling) and by the FTC (for product advertising). Enforcement measures are based mainly on these agencies' own monitoring of the marketplace, but also on complaints received from consumers and competitors. These measures are mainly non-judicial, consisting of warning letters that FDA and FTC officials indicate usually produce a corrective action by product manufacturers, but the government can and does initiate judicial action when its warnings are not met.

Federal enforcement efforts are supplemented by enforcement at other levels of government, such as the attorneys general of some of the 50 states and local consumer protection bureaus. In addition, a number of membership-based organisations try to perform some monitoring of food and supplement product claims (and whether they are valid) as a service to their members.

The number and strength of the administrative and judicial enforcement mechanisms available under the U.S. system would suggest that the level of consumer protection is quite high. Indeed, the FTC and FDA can bring to bear a wide and impressive range of sanctions and leverage against offending companies, and judicial remedies include cease-and-desist orders, consent agreements forcing the company to refrain from certain action, and even court-ordered compensation to affected consumers.

However, partly due to resource limitations, regulators tend to seek such remedies only in cases where a company has demonstrated a pattern of misconduct. Moreover, there is considerable concern that enforcement authorities' resources are increasingly inadequate to cope with the sheer number of products and claims being made for them. This concern has become especially acute because of a recent upsurge in the marketing of such products on the Internet, especially dietary supplements.

E. MEANS OF COMMUNICATION

The two main regulatory authorities – the FDA and the FTC – apply the same standards to nutrition and health claims regardless of the means by which they are communicated. It should be noted, however, that much of the FTC's recent enforcement activity (problems) has been directed towards the numerous claims being made via Internet marketing sites.

F. CONSUMER PROTECTION

The U.S. regulatory approach has evolved over a time frame in which consumer knowledge of the health and nutrient value of food and related products has grown substantially. That knowledge plays an increasingly decisive role in the products that consumers select, and where manufacturers recognize the potential value of nutrition and health claims in distinguishing their products from those of their competitors. These trends are reflected in the gradual movement towards mandatory nutrition labelling, and the accompanying concern that consumers should be able to rely on the validity and accuracy of nutrition, health and related claims when they appear on labels or in product advertising.

As noted above, many parties agree that the level of consumer protection regarding such claims was quite high during the period when prior FDA approval for claims was

required. There is considerable concern, however, that this level of protection has fallen off in the last several years as Congress has moved to create alternative bases upon which claims can be made without prior FDA approval. The dietary supplements industry is seen as having been particularly assertive in making structure/function claims for the rapidly growing number of supplements on the U.S. market.

G. BARRIERS TO TRADE

Over this same period, industry has been concerned at times that the U.S. regulatory approach failed to allow them sufficient leeway in making nutrition and health claims, which they believe are of great value to consumers seeking to make an informed purchasing choice. This was particularly true of the dietary supplement industry, which felt that the overall approach of regulatory authorities in the early 1990s was constraining the growth of an industry in which many Americans see great value.

The reforms adopted from 1994 to 1997 are widely viewed as having helped to engender increased competition in the food and dietary supplement markets. In many respects, this has achieved the goal policymakers wanted: to allow the food and supplement industries to grow, and to make their products more widely available to consumers who may wish to use them.

To date, the degree to which the U.S. system might prevent the fair marketing of claims-bearing products from elsewhere has not received substantial attention. On the other hand, many of those interviewed suggested that the increasing saturation of the U.S. market, specifically for dietary supplement products, will soon lead to an increase in U.S. exports of such products. At this point, the claims that such products bear could become an issue in several export markets.

H. CASE LAW

Jurisprudence in the U.S. related to the making of nutrition and health claims has fallen generally into two categories: first, cases challenging broad aspects of the U.S. regulatory regime itself, including whether some aspects are constitutional or not, and secondly, cases involving administrative and court enforcement efforts against particular companies thought to be infringing one or more of the relevant laws.

I. STAKEHOLDER ANALYSIS

1. Government Authorities

- The United States has one of the world's most detailed regulatory schemes for nutritional and health claims. In spite of this, the U.S. authorities continue to struggle to achieve the ideal balance between ensuring a high level of consumer protection and giving industry the leeway to make all the valid claims that it would like.

2. Enforcement Authorities

- Enforcement responsibilities are split between the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC). However, the two agencies work in close cooperation on enforcement issues in order to make the enforcement system effective. Since 1994, FTC has modeled its advertising enforcement policy on the FDA's labelling standards.

3. Consumers

- Many consumer groups have tried to oppose the expansion of the basis upon which specific health claims may be used in food, but to no avail. Their argument, based on the idea that consumers would be exposed to a growing number of misleading or unsubstantiated claims, has not been retained by the US government. Thus, consumer organizations tend to believe that the government favors the industry to the detriment of consumers.

4. Industry

- Industry groups have widely supported the expansion of the basis upon which specific health claims may be used in food. They believe that the increase in the number of permissible claims was an effective way of providing consumers with information on the products that they buy.

- To conclude, it should be underlined that there is considerable concern in the US that in allowing legitimate industry greater flexibility to make certain claims with no prior approval, some less reputable manufacturers have also been given room for maneuver, resulting in an increase in questionable claims (for sometimes questionable products). This concern is exacerbated by the increasing use of the Internet as a marketing tool, especially for dietary supplements. The combined effect of more liberal procedures for making claims and a mechanism providing vastly wider dissemination of such claims has created the risk that many questionable claims now lie beyond the effective reach of regulatory authorities.

*** * ***

II. MEMBER STATE POLICY

A. DEFINITIONS OF CLAIMS

1. Nutritional Claims

The U.S. Code of Federal Regulations codifies the definitions and other elements of legislation governing the making of nutritional and health claims. Title 21 §101.13 of the Code of Federal Regulations (CFR) distinguishes between expressed nutrient content claims and implied nutrient content claims.

An expressed nutrient content claim is defined as *any direct statement about the level (or range) of a nutrient in the food (e.g. "low sodium" or "contains 100 calories").*[59]

An implied nutrient content claim is defined as any claim that

- *describes the food or an ingredient therein in a manner that suggests that a nutrient is absent or present in a certain amount (e.g. "high in oat bran"), or*

- *suggests that the food, because of its nutrient content, may be useful in maintaining healthy dietary practices and is made in association with an explicit claim or statement about a nutrient (e.g. "healthy, contains 3 grams of fat").*[60]

These definitions apply to foods that are intended for human consumption and that are offered for sale, including both conventional foods and dietary supplements (even though these two categories are subject to somewhat different regulatory schemes).

2. Health Claims

According to Title 21 §101.14 CFR, a health claim is *any claim made on a label or in labelling of a food, including a dietary supplement, that expressly or by implication, including "third party" references, written statements (e.g., a brand name including a term such as "heart"), symbols (e.g., a heart symbol), or vignettes, characterizes the relationship of any substance to a disease or health-related condition. Implied health claims include those statements, symbols, vignette or others forms of communication that suggest, within the context in which they are presented, that a relationship exists between the presence or level of a substance in the food and a disease or health related condition.*[61]

[59] Code of Federal Regulations, Title 21 (Food and Drugs), Nutrient Content Claims – general principles, Sec. 101.13(b)(1).
[60] Code of Federal Regulations, Title 21 (Food and Drugs), Nutrient Content Claims – general principles, Sec. 101.13(b)(2).
[61] Code of Federal Regulations, Title 21 (Food and Drugs), Health Claims – general requirements, Sec. 101.14(a)(1)

3. Structure/Function Claims

The U.S. regulatory scheme also allows a sub-category of claims known as structure and function claims (e.g., "calcium builds strong bones"). These are defined by U.S. law as any claim that *describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans,* or that *characterizes the documented mechanism by which a nutrient or dietary ingredient act to maintain such structure or function.*[62]

4. Ethical Claims

Because there is not a comprehensive regime for regulating the making of ethical claims, these are not specifically defined in U.S. law.

B. LEGISLATION IN PLACE

The United States has a comprehensive and highly detailed regulatory scheme governing the making of nutrition-related claims and health claims on food product labelling or in separate advertising. The U.S. regulatory regime has long imposed a general obligation that label statements be truthful. More recent legislation has clarified substantially the kinds of claims that can be made for particular types of products, especially foods and dietary supplements.

The following are the most relevant statutes on health and nutrition claims made on product labels, which represent successive amendments to the federal Food, Drug and Cosmetic Act. The provisions of these measures are reflected in implementing regulations that are codified at Section 21 §101 of the Code of Federal Regulations (CFR):

- the Nutrition Labelling and Education Act (NLEA), 1990
- the Dietary Supplements Health and Education Act (DSHEA), 1994
- the Food and Drug Administration Modernization Act (FDAMA), 1997

Taken together, these and other federal statutes give the FDA primary responsibility for regulating claims made on product labels, which includes product packaging, inserts, and other promotional materials that are distributed along with the product at the point of sale (e.g., informational pamphlets placed alongside the product on retail store shelves). By law, the FDA also shares enforcement authority over product advertising with the FTC. In practice, however, the two agencies cooperate based on a memorandum of understanding between the two that places primary responsibility for enforcement regarding product advertising with the FTC.

According to Sections 5, 12 and 15 of the Federal Trade Commission Act, the FTC has responsibility for regulating claims made in food and dietary supplement advertising (and, indeed, in product advertising generally). Such advertising includes

[62] 21 U.S.C. 4039(R)(6)(a)

print and broadcast ads, infomercials, catalogues and similar direct marketing materials.[63]

While it appears that regulatory authority is, therefore, split depending on whether the claim is made in product labelling or in product advertising, the two agencies work together closely on enforcement issues. Indeed, the FTC has modeled its advertising enforcement policy on the FDA's labelling standards (see Enforcement Policy Statement on Food Advertising, May 1994, annex I).

1. Nutritional Claims

a. Nutrient Content Claims

Under the Nutrition Labelling and Education Act (1990), companies could not use a nutrient content claim in food labelling unless the FDA published a regulation specifically authorizing such a claim. Consumer groups generally preferred this approach on the grounds that it set a high standard for consumer information and protection, but many in the food industry viewed this approach as too restrictive.

It should be noted that an even stricter regime applies to certain special categories of food such as food for infants or children under 2 years of age, where nutrient content claims (except for statements regarding the percentage of recommended daily intake of vitamins and minerals) are generally not allowed. It should also be noted that the NLEA implementing regulations initially exempted restaurant menus from the general requirements applicable when a nutrition or health claim is made. Over time, however, the FDA was persuaded that U.S. consumers' awareness of the relationship between diet and health would be improved if menu claims were also covered, and it eliminated the restaurant exemption in 1996.

Two provisions of the 1997 Food and Drug Administration Modernization Act (FDAMA), Sections 303 and 304, created an alternative approach to authorizing nutrition claims. These allow companies to use nutrient content claims if they are based on current, published authoritative statements of one or more federal scientific bodies that have responsibility for public health protection or research on human nutrition.

FDAMA specifically identified the National Institutes of Health and the Centers for Disease Control and Prevention as relevant scientific bodies. The FDA considers that the following federal agencies also qualify: the Office of the Surgeon General in the Department of Health and Human Services, and, in the Department of Agriculture, the Food and Nutrition Service, the Food Safety and Inspection Service, and the Agricultural Research Service. Thus, manufacturers may rely on statements made in current, published reports by these bodies as the basis for a nutrient content claim.

Companies must notify FDA of their intent to use a claim on the basis of such an authoritative statement. The notification must include the exact wording of the proposed claim, a description of why the manufacturer believes the scientific body's

[63] It should be noted that the FTC has asserted jurisdiction over promotional materials on the Internet, which the FTC regards as another means of advertising. Similarly, the FDA believes that product-related claims made on the Internet can be considered as another form of product labelling.

authoritative statement justifies making the claim, and a copy of the authoritative statement on which the claim is based. For nutrient content claims, the notification must also include a balanced representation of the scientific literature relation to the nutrient level to which the claim refers.

Notification of the prospective nutrient content claim must be submitted to FDA at least 120 days before a food bearing the claim may be introduced into interstate commerce. The claim can then be used if FDA does not modify it or prohibit it within this timeframe. (FDA may prohibit the claim either by issuing a regulation or obtaining a federal court injunction against its use). These provisions apply to claims made both on conventional food and dietary supplements.

b. Comparative Claims

All comparative claims must be accompanied by a declaration stating the percentage or fraction of change and the identity of a reference food (e.g. "50% less fat than potato chips"). The reference food varies depending on the particular claim made. To make use of the terms "less," "fewer," or "more," for example, the reference food may be a dissimilar food within a product category that can generally be substituted for one another such as potato chips as a reference for pretzels. To make use of terms such as "light," "reduced," "fortified," and "enriched," however, the reference food needs to be a similar one, such as another kind of potato chips. The declaration stating the percentage or fraction of change, and the identify of the reference food, must appear in immediate proximity to the most prominent claim.

c. Other Nutrient Content Claims

The FDA has also specified in detail the conditions under which other popular labelling terms can be used. The term "lean," for example, may be used on seafood and game meats only if the product contains less than 10 grams of total fat, less than 4.5 grams of saturated fat, and less than 95 milligrams of cholesterol per reference amount. The term "modified" may be used as a comparative claim in a statement of identity of the product (e.g., Modified Fat Cheese Cake – contains 35% less fat than our regular cheese cake").[64]

Similarly, the FDA has established a scale specifying the percentage daily amount of protein, vitamins, minerals, dietary fiber and potassium that a product must provide before its labelling can contain comparative terms such as "Rich in" or "Extra." For example, a product must provide more than 20% of the daily value of these items to be able to use the terms "High," "Rich in," or "Excellent source of," and must provide between 10-19% of the daily value to be able to use the terms "Good source of," "Provides," or "Contains." So long as the labeled food and the reference food can both be considered a "good source" of a particular nutrient, the FDA also allows what it calls "equivalence" claims (e.g., "contains as much vitamin C as an 8 ounce glass of orange juice").

[64] See "A Food Labelling Guide," Relative (or Comparative) Claims, Annex B, which was published in September 1994 and updated in May 1997 by the Center for Food Safety and Applied Nutrition of the U.S. Food and Drug Administration, which is attached as Annex II.

Finally, the FDA has specified certain labelling statements that are not considered claims, so long as they are not made in a nutrient context. These include statements enabling consumers to avoid a particular product for religious, food tolerance or other non-nutrition related reasons (e.g., "100% milk-free), statements about non-nutritive substances (e.g., "made with no artificial colors"), and so-called added value statements (e.g., made with real butter).

d. Health Claims

The Nutrition Labelling and Education Act (1990) directed the Food and Drug Administration to promulgate regulations establishing a regulatory regime under which FDA had to give prior authorization to health claims before they could be used. Until the 1997 Food and Drug Administration Modernization Act, which created an alternative approach based on authoritative statements by federal scientific bodies, this was the only basis on which health claims could be made.

Under this system (which is still an option for companies wishing to make a health claim), manufacturers are obliged to petition the FDA to authorize a specific claim. Petitions must include a complete explanation of why the substance qualifies for a health claim, including a summary of the scientific data upon which the claim is based and a statement of the public health benefit if the claim is approved. The petition must also address whether there is an optimum level of the substance that should be used, and whether the substance can cause adverse effects for any segment of the population. If the substance is intended for a specific segment of the population (e.g., adolescents or the elderly), the dietary evidence produced must be specific to that segment.[65]

If the FDA determines that the claim is valid, it will issue a regulation that allows any product of that type to make the claim. (The regulation, therefore, is generally not intended to be specific to one or several manufacturers' products. However, consumer groups have criticized the FDA decision that authorizes a health claim for fiber from whole oats on the grounds that it would supposedly benefit mainly one manufacturer, and leveled a similar criticism for the authorization given to health claims for fiber from psyllium).

In making its declaration, FDA imposes a standard of "significant scientific agreement" about the claim. Thus, FDA may issue regulations authorizing a specific claim only if the agency *determines, based on the totality of publicly available evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.*[66]

The FDA has also made clear that it does not believe this standard would be met by any findings that could be characterized as preliminary research results or that suggest

[65] See Code of Federal Regulations,Section 101.70, Petitions for Health Claims.
[66] See Section 403(r)(3)(B)(i) of the Food and Drug Administration Modernization Act.

the research is less than conclusive. (As explained below, however, the effectiveness of these standards has come into question as a result of recent court rulings).

Seven health claims were authorized under this system in 1993, and three others have been added since. These claims refer to:

- Calcium and osteoporosis
- Sodium and hypertension
- Dietary lipids and cancer
- Dietary saturated fat and cholesterol and risk of coronary heart disease
- Fruits, vegetables and grain products that contain fiber and risk of coronary heart disease
- Fruits/vegetables and cancer
- Folate and neural tube birth effects
- Dietary sugar alcohol and dental caries
- Dietary soluble fiber from whole oats or psyllium products and coronary heart disease

With respect to each of the above, federal regulations specify in detail the types of claims that can be made and the limitations to the claim that must be spelled out. For example, a claim associating calcium with a reduced risk of osteoporosis may be made only if these conditions are met:

- The claim makes clear that there are risk factors for this disease (e.g., heredity, gender, race, age and amount of exercise) other than the amount of the calcium intake;
- The claim does not suggest that all members of the U.S. population are equally at risk from osteoporosis, and identifies the sections of the population who are;
- The claim does not attribute a specific degree of risk reduction to calcium intake; and
- The claim states that there is no known benefit to a calcium intake higher than 200% of the recommended daily intake.

Similar conditions and limitations apply to the nine other health claims mentioned above. These conditions and limitations appear in Annex III.

As noted above, two new provisions of the 1997 Food and Drug Administration Modernization Act (Sections 303 and 304) also allow companies to use health claims for foods if they are based on authoritative statements of one or more federal scientific bodies.[67] As with nutrient content claims, the notification must include the exact wording of the proposed claim, a description of why the manufacturer believes the scientific body's authoritative statement justifies making the claim, and a copy of the authoritative statement. In the case of health claims, the notification must also include a balanced representation of the scientific literature relating to the relationship between a nutrient and the disease or health-related condition the nutrient is meant to affect.

[67] As explained in Section II.E.2, below, the FDA believes that the Food and Drug Administration Modernization Act does not explicitly allow for the use of health claims based on authoritative statements for dietary supplements, but has initiated a rule-making procedure that would accomplish this.

Companies must notify FDA of their intent to use a health claim on the basis of an authoritative statement. Notification of the prospective health claim must be submitted to FDA at least 120 days before a food bearing the claim may be marketed in more than one state.[68] The claim can then be used if FDA does not modify it or prohibit it within this timeframe. (FDA may prohibit the claim either by issuing a regulation or obtaining a federal court injunction against its use).

e. Structure and Function Claims

Longstanding U.S. regulatory policy had generally permitted the making of structure and function claims for food products. (Examples of such claims include: *calcium builds strong bones, anti-oxidants maintain cell integrity, fiber maintains bowel regularity).* In 1994, the Dietary Supplement Health and Education Act was adopted, helping to clarify the circumstances in which "structure and function" claims can be made for dietary supplements.

Under this Act, structure and function claims may be made without prior FDA approval, but must be notified to the FDA within 30 days after the product is first marketed. Manufacturers must be able to substantiate their claims but do not have to share the substantiation with FDA or make it publicly available in advance. When a structure or function claim is made for foods, the substance that is the basis of the claim must contribute to the aroma, taste or nutritive value of the food. When such a claim is made for a dietary supplement, such products must carry the following disclaimer on the label: *This treatment has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent disease.*

With respect to both foods and dietary supplements, structure and function claims must meet the general statutory requirement that they not be false or misleading. Claims which pretend that a nutrient or dietary ingredient contained in a dietary supplement can help to diagnose, cure, mitigate or prevent a disease are unlawful, unless they are appropriate health claims authorized by FDA (see list above) or if the dietary supplement is marketed as a drug (in which case the product has to comply with the more stringent provisions of the Food, Drug and Cosmetic Act). Examples of illegal claims that are not allowed include: *cures cancer or treats arthritis.*

The FDA initially issued procedures for manufacturers to notify the FDA of their intent to make a structure/function claim in October 1997. Since that time, the FDA received more than 3,000 notifications of structure/function claims.

D. EXISTING PROHIBITIONS, RESTRICTIONS AND EXEMPTIONS

The circumstances in which nutrition and health claims may be used have been set forth in general terms above. As explained, the current U.S. regulatory framework establishes detailed procedures for obtaining prior authorization for such claims

[68] In general terms, the authority of the federal government to regulate trade in goods derives from the fact that the goods are marketed across state lines and therefore have an effect on interstate commerce.

(where needed), as well as detailed standards for being able to make such claims even when prior authorization is not required.

The main prohibition in U.S. law relating to product labelling specifically prohibits the introduction of food products that have been "misbranded." A product is considered to have been misbranded if its labelling is false or misleading in any particular way, or if its advertising is false or misleading in a material respect. [69] The main prohibition in U.S. law relating to product advertising prohibits unfair or deceptive practices in (or affecting) interstate commerce,[70] including the dissemination of false and misleading advertising intended to induce consumers to purchase particular foods or related products.[71]

Some of the other specific prohibitions arising from the current U.S. regulatory framework include the following.

1. Nutritional Claims

According to Title 21 CFR §101.13:

- nutrient content claims are not allowed on food intended specifically for use by infants and children of less than 2 years of age, except for claims regarding vitamins and minerals or when the claim is specifically provided for in parts 101, 105 and 107 CFR.

- because the use of a "free" or "low" claim before the name of a food implies that the food differs from other foods of the same type by virtue of its having a lower amount of the nutrient, only foods that have been specially processed, altered, formulated or reformulated so as to lower the amount of nutrient in the food, remove the nutrient from the food or not include the nutrient in the food can bear such a claim.

- to bear a relative claim about the nutrient, the amount of that nutrient in the food must be compared with an amount of nutrient in an appropriate reference food, as specified in 21 CFR §101.13 (j) (1).

- nutrient content claims that have not been defined by regulation and that are contained in the brand name of a specific product that was the brand name in use on such food before October 25, 1989 may continue to be used as part of that brand name for such product, provided that they are not false or misleading.

- a soft drink that used the term *diet* as part of its brand name before October 25, 1989 may continue to use that term as part of its brand name, provided that it is not false or misleading. A statement that describes the percentage of a vitamin or mineral in the food in reference daily intake may be made without a regulation authorizing such a claim for a specific vitamin or

[69] See the Federal Food, Drug and Cosmetic Act, Sec. 403(a)(1). Annex IV.
[70] See the Federal Trade Commission Act, Sec. 5
[71] See the Federal Trade Commission Act, Sec. 12

mineral, unless such a claim is expressly prohibited by regulation under section 403(r) (2) (A) (6)

2. Health Claims

The following health claims are not authorized for foods in conventional forms or for dietary supplements of vitamins, minerals, herbs or other similar substances:

- dietary fiber and cancer
- dietary fiber and cardiovascular disease
- antioxidant vitamins and cancer
- zinc and immune function in the elderly
- omega-3 fatty acids and coronary heart disease

In addition, claims made about the use of a dietary supplement to diagnose, cure, mitigate or prevent a disease are not allowed (see above C part 2).

E. POLICY DEVELOPMENTS AND STAKEHOLDERS' POSITIONS

1. Evolution of Policies Governing Nutritional Claims and Health Claims

Over the past three decades, U.S. policy toward the making of nutritional and health claims on food products and in related advertising has evolved considerably. This has reflected both the growing desire of consumers to make an informed choice about the foods they select, as well as a growing recognition by food manufacturers that such claims offer a potentially important means of informing consumers and distinguishing their products from those of their competitors.

The importance of nutrition, and the contribution that nutrition labelling can make to consumers' health, took on a higher visibility in the late 1960s, especially in the wake of the 1969 White House Conference on Food, Nutrition and Health. In the early 1970s, the U.S. Food and Drug Administration began to establish a regulatory framework governing nutrition labelling on foods. In general terms, that early framework allowed food manufacturers to provide nutritional information on product labels on a voluntary basis, but established a standard format in which the information was to be presented when manufacturers chose to do so. Nutrition labelling was mandatory only in certain cases, such as when the product made a specific nutrition claim or when a nutrient had been added.

Consumer awareness was further enhanced with the publication in 1988 of the Surgeon General's "Report on Nutrition and Health", the first comprehensive federal chronicle of the importance of diet to health. In 1989, the Food and Nutrition Board of the National Academy of Sciences (NAS) convened a panel to examine how food labels could be improved to help consumers move towards healthier diets.

Based partly on the NAS panel findings, the United States moved to a system of mandatory nutrition labelling with the adoption in 1990 of the Nutrition Labelling and

Education Act (NLEA).[72] The NLEA required mandatory nutrition labelling for most foods and specified the circumstances in which health-related claims could be made on food products.

Adoption of the NLEA reflected a growing awareness of the importance of a healthy diet, and was intended to help promote informed consumer choice about food products. It was also intended to encourage the development of new food technologies, which legislators felt would lead, in turn, to an increase in claims made about foods produced with those technologies. After a long public consultation process, regulations implementing the nutrition labelling provisions of the NLEA took effect in 1994.

Along with nutrition claims, health claims became a sensitive issue in the U.S. during the 1980s, when food marketing strategies began to reflect greater interest in the role of nutrition in promoting public health. In the absence of regulation, some manufacturers used claims that were considered misleading by consumers. The 1990 NLEA was partly designed to protect consumers by preventing deceptive and misleading health claims on product labels. Thus, the Act required prior FDA approval for any health claims, and directed the Secretary of Health and Human Services (who oversees the FDA) to determine whether 10 specific health claims should be allowed. Regulations implementing the NLEA provisions governing health claims took effect in 1993, and FDA has gradually authorized 10 specific health claims.

In addition to regulating nutrition and health claims, the NLEA had a broader purpose. Congress intended health and nutritional claims to help educate consumers, so as to assist them maintain healthy dietary practices. Thus, NLEA mandated the FDA to undertake a consumer education effort that incorporates mandatory nutrition labels and emphasizes the importance of diet to overall health.

In 1994, the U.S. Congress adopted legislation devising a new regulatory framework for dietary supplements, which had previously been regulated in the U.S. as foods (or in some cases as drugs). Market research indicates that U.S. consumer spending on dietary supplements had grown from $3.3 billion in 1990 to $5 billion by 1994.[73] The Dietary Supplement Health and Education Act (DSHEA)[74] was designed to help ensure that such products were available to consumers, many of whom believe that such supplements offer health benefits, and that manufacturers could market them more freely so long as they could verify the claims made about the product.

In 1997, the U.S. Congress adopted legislation expanding the basis upon which specific health claims may be used in foods. As an alternative to obtaining prior FDA approval, the Food and Drug Administration Modernization Act allowed

[72] Public Law 101-535, the Nutrition Labelling and Education Act, which is attached at Annex V. This act is augmented by roughly 1,000 pages of implementing regulations published in the Federal Register and available from the Government Printing Office. The full implementing regulations are not included in annex to this report, but their content is reflected in the U.S. Code of Federal Regulations, the relevant portions of which are attached at Annex VI.

[73] A 1998 survey of industry by the National Business Journal suggested that this number had grown to $12 billion annually.

[74] Public Law 103-417, the Dietary Supplement Health and Education Act, which is attached at Annex VII.

manufacturers to make health claims when the claim is based on an authoritative statement by one of several federal scientific bodies (e.g., the National Institutes of Health, the National Center for Disease Control, and the National Academy of Sciences). In such cases, the FDA is given a limited period of time to object to the making of the claim and to demonstrate why it should not be made. (Because it believes that, for health claims, conventional foods and dietary supplements should be subject to the same standards, the FDA has made a proposal to allow supplement manufacturers to also make health claims based on the authoritative statements of federal scientific bodies).

This change was broadly supported by many food manufacturers, which view health claims as an effective way of providing consumers with information on the products they buy. However, many consumer groups opposed this change, believing that it would result in consumers being exposed to a growing number of claims that would not be fully substantiated, and that – together with the DSHEA – it represented the latest in a series of regulatory changes tilting public policy on food and supplement labelling heavily in favor of industry.

Partly as a result of this evolution in policy, recent evidence suggests that U.S. consumers' interest and awareness of the link between diet and health has reached an all time high. An independent survey, conducted early this year for the Food Marketing Institute, found that 90% of consumers believe that a healthy diet contributes directly to disease prevention.[75] More than two-thirds said that they regularly purchase fortified foods to help maintain good health, and one-third said that they bought organic foods for the same reason. Reducing or controlling their weight was reported by 72% of those surveyed as the single most important factor in their food purchases, while 72% also cited cholesterol as a key concern.

2. Ethical Claims

As noted above, the U.S. Government has not adopted a regulatory scheme specifically governing the making of ethical claims. If such claims are made, they would, of course, be subject to the general requirement of U.S. law that they be truthful and not misleading. However, officials at the U.S. Federal Trade Commission (FTC), which enforces the truth-in-advertising law,[76] indicate that no such cases have arisen.

There has been a small amount of activity in areas that some believe could fall under a very broad definition of ethical claims. For example, the FTC has adopted guidelines governing the use of environmental claims in product marketing, and was petitioned several years ago by consumer organizations to develop comparable guidelines governing the use of claims that products were manufactured without testing on animals. The FTC declined to take up this petition, however, and its officials indicate they have not been pressed to adopt guidelines on social or other ethical claims.

[75] See "Shopping For Health: The Growing Self-Care Movement," published jointly by the Food Marketing Institute and Prevention magazine, June 1999.

[76] Sec. 5 of the Federal Trade Commission Act prohibits deceptive practices affecting interstate commerce, including deceptive advertising. Sections 12 and 15 of the Federal Trade Commission Act prohibit false advertising relating to foods, drugs and medical devises, and this includes advertising that is misleading in any material respect.

Some consumer groups believe that U.S. industry has effectively quashed any consideration by government of a regulatory scheme governing such claims.

3. Review of Current Policy Developments

Recent policy initiatives affecting the U.S. regulatory scheme have mainly been aimed at clarifying the regulatory treatment of dietary supplements. These initiatives have focused on two areas: first, FDA efforts to grant explicit authority for the use in dietary supplements of health claims based on authoritative statements of federal scientific bodies, and second, on FDA efforts to clarify the difference between structure/function claims and health claims.

4. Structure/Function Claims v. Health Claims in Dietary Supplements

Since the adoption in 1994 of the Dietary Supplement Health and Education Act, the FDA has been attempting to devise and clarify implementing regulations. This is to make clear what is permitted as a structure/function claim, and clarify the sometimes narrow distinction between structure/function claims and health claims.

The FDA issued a proposed rule in April 1998 seeking to accomplish these objectives, and in particular, to distinguish structure/function claims from regulations suggesting disease prevention or cure. As part of the proposed rule, the FDA recommended a definition of "disease" that differed from the definition of "disease or health-related condition." This had been in force as a working definition since 1993, when the FDA issue regulations implementing the health claims provisions of the Nutrition Labelling and Education Act.[77]

This proposed rule sparked off a substantial reaction from industry, consumer organizations, and other interested parties, in the course of which the FDA received more than 100,000 comments. Among these, according to the FDA, three issues received particular attention:

- whether the FDA should retain the currently applied definition of "disease of health-related condition" or switch to the newer one it has proposed (but which generated considerable opposition),
- whether certain common conditions associated with natural states (such as hot flashes associated with menopause) should be included in any new definition of "disease," and,
- whether dietary supplements should be permitted to carry implied disease claims.

In the wake of the many adverse comments generated by its proposed rule, the FDA believes that further public consultation is necessary before settling on a final version. To that end, the FDA has engaged in a series of public meetings, in 1999, at which stakeholders have been invited to testify in detail about their views of the proposed rule and possible alternatives. The most recent of these were held in June and August

[77] See "Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body," Food and Drug Administration, Federal Register Vol. 63, No. 82, Wednesday, April 29, 1998, p. 23624. Annex VIII.

1999, and the results bear close monitoring for their potential impact on the U.S. regulatory scheme for dietary supplements.

5. Use in Dietary Supplements of Authoritative Statements By Federal Scientific Bodies

As noted above, the 1997 Food and Drug Modernization Act (FDAMA) permitted nutrient content claims based on authoritative statements of federal scientific bodies for both conventional foods and for dietary supplements. For conventional foods, FDAMA also allowed health claims based on such authoritative statements, but did not explicitly allow health claims based on authoritative statements for dietary supplements.

FDA believes that, with respect to health claims, conventional food and dietary supplements should be subject to the same standards and procedures. It therefore issued a proposed rule in January 1999 that would allow health claims based on authoritative statements to be made for dietary supplements.

In so doing, however, the FDA does not believe that dietary supplement manufacturers are likely to make substantial use of health claims based on authoritative statements. As noted above, the FDA feels that supplement manufacturers are more likely to rely on structure/function claims than on health claims. FDA estimates, for example, that 12 companies per year may submit an average of five notifications each that they plan to use a health claim based on an authoritative statement. If the FDA estimate is correct, the resulting total of 60 notifications per year would be dwarfed by the 3,000 notifications of structure/function claims that the FDA has received in the past two years.[78]

III. VOLUNTARY INSTRUMENTS

A. VOLUNTARY INSTRUMENTS IN PLACE

1. Nutritional Claims and Health Claims

At times during the late 1980s and 1990s, there was some hope on the part of federal regulators that the food industry and, also the dietary supplement industry, would launch a comprehensive push towards self-regulation that would include regulation of product labelling and advertising. Self-regulation was not viewed by regulators as a complete alternative to federal oversight of the industry, but rather as a possible complementary regime that would spread the burden of the oversight role, and lessen the load of the regulatory agencies on enforcement.

A number of consumer and membership-based organisations perform some monitoring of nutrition and health claims, either as a basis for their lobbying efforts on related policies or, in the case of certain membership-based organisations, as a

[78] For further detail on the FDA's comparative estimates of structure/function claims versus anticipated health claims based on authoritative statements, see "Food Labelling: Use on Dietary Supplements of Health Claims Based on Authoritative Statements, Federal Register Vol. 64, No. 13, January 21, 1999. Annex IX.

service to their members. Segments of the food and dietary supplement industries have also put into place codes of conduct that deal mainly with such issues as product safety and quality, and goods manufacturing practices. However, due partly to the comprehensive nature of the federal regulatory regime (and parallel enforcement efforts by attorneys general among the 50 states), the industries have not developed a comprehensive, voluntary code of conduct on nutrition and health claims.

IV. VERIFICATION SYSTEMS

A. CRITERIA FOR SUBSTANTIATING CLAIMS

1. Nutritional Claims and Health Claims

As explained above, nutrition and health claims for foods may be based either upon prior approval of the claim by the Food and Drug Administration, or upon authoritative statements by federal scientific bodies.[79] Both methods reflect criteria that seek to ensure the claims meet a minimum threshold of scientific support.

In the case of claims made on the basis of authoritative statements by federal scientific bodies, the claims must:

- come from a "federal scientific body of the United States with official responsibility for public health protection or research directly related to human nutrition" or from the National Academy of Science or its subdivisions.

- be published by the scientific body and be currently in effect.

- identify the nutrient level to which the claim refers.

- reflect a consensus within the identified scientific body. It cannot be a statement made individually by an employee of a federal scientific body.

- be based on a deliberative review of the scientific evidence by the scientific body.

In considering whether to grant prior approval to health claims for foods and dietary supplements, the Food and Drug Administration requires that there be "significant scientific agreement" about the claim. Under this standard, FDA may issue regulations authorizing a specific claim only if the agency *determines, based on the totality of publicly available evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.*[80] The FDA has also made clear that it does

[79] The situation is the same for dietary supplements, except that the FDA is still in the process of promulgating regulations allowing claims for supplements to be based on authoritative statements.
[80] See Section 403(r)(3)(B)(i) of the Food and Drug Administration Modernization Act.

not believe this standard would be met by any findings that could be characterized as preliminary research results or that suggest the research is less than conclusive.

However, the FDA standard has recently been called into question by a decision of one of the nation's most influential courts of appeal.[81] The appeal court's ruling involved an attempt by dietary supplement manufacturers to reverse an FDA decision rejecting four health claims that the manufacturers had proposed. In its ruling, the court held that the FDA had acted arbitrarily in rejecting the proposed claims because it had failed to sufficiently clarify what was required by the standard "significant scientific agreement."[82] As a result, the FDA could be forced to provide the public with substantially greater detail about the quality, amount and conclusiveness of the scientific evidence needed to support a health claim.

Moreover, the appeal court held that the FDA decision had violated the manufacturers' right to free speech (which includes the right to lawful and non-misleading commercial speech) by prohibiting the health claims outright instead of considering the alternative sought by the plaintiffs. This would in effect allow claims, but would require them to be accompanied by disclaimer statements. The impact of this part of the court ruling is not yet clear, but it creates the possibility that the FDA could be forced to authorize health claims even when its scientific standard has not been fully met, so long as the health claim is accompanied by a statement that accurately reflects the level of scientific uncertainty about the claim.

2. Structure and Function Claims

As explained above, the FDA has proposed a rule that seeks to clarify the types of statements that would qualify as structure/function claims for dietary supplements. However, this rule does not seek to establish a standard for substantiation of structure/function claims and some consumer groups have complained that the FDA has not done so at all. The reasoning of the appeals court ruling described above, however, would suggest that the FDA will have to establish a precise substantiation standard.

B. LEGAL/ADMINISTRATIVE SYSTEMS FOR VERIFYING CLAIMS

1. Pre-Clearance Rules/ Guidelines

As explained in an earlier Section, the U.S. regulatory system contains a detailed pre-clearance process by which prior approval of the FDA can be obtained for nutrition and health claims. (See that Section of the report for a detailed review of the process and the supporting material that manufacturers must provide when seeking prior approval of a claim.) The FDA has also issued a guidance document setting forth the procedures for manufacturers to notify the FDA of their intention to make a claim based on an authoritative statement by a federal scientific body. Much of this

[81] In the U.S. judicial system, the federal courts of appeals occupy a middle strata between the federal district courts, which is where most cases are initially heard, and the U.S. Supreme Court, which is the country's highest judicial body. The U.S. Court of Appeals for the D.C. Circuit is widely regarded as the most authoritative appeals court on issues involving federal legislation and regulation.

[82] Pearson v. Shalala, 164 F.3d 650 (D.C. Circuit), 1999, rehearing *en banc* denied, 172 F.3d 72 (D.C. Circuit) 1999.

guidance is reflected in the earlier Section, and the guidance document itself is attached as an annex .

2. Post-Clearance Rules/ Guidelines

The U.S. regulatory system includes monitoring and enforcement efforts by federal agencies of food and dietary supplement manufacturers' compliance with federal law and regulations on nutrition and health claims.

As explained above, the U.S. Food and Drug Administration has primary authority for enforcement relating to claims made on product labels. According to FDA officials, most instances involving questionable labelling claims are resolved via informal (i.e., non-judicial) means. Specifically, the FDA regularly sends various types of warning letters alerting manufacturers to the possibility that their product labelling may not be in compliance with FDA regulations, and that continued use of the label in question could result in more formal enforcement proceedings.[83] Officials indicate that such letters result in corrective action by the manufacturer (either cessation of use of the label or modification of its text) about 90% of the time, and that the FDA only rarely undertakes judicial enforcement efforts.

In matters involving product advertising, the Federal Trade Commission has primary enforcement authority. As with the FDA, officials of the FTC indicate that that the vast majority of instances involving questionable advertising are resolved by informal means. The FTC also regularly sends what it calls "access letters" to manufacturers alerting them to the possibility that their advertisements may not be in compliance with federal law and regulation. According to the FTC, such letters result in corrective action about 98% of the time. The FTC also enters into consent agreements with manufacturers in which they pledge to undertake specific steps conforming their behavior to FTC rules. FTC officials indicate that they rarely undertake judicial enforcement proceedings.

FTC officials also indicate that an important share of their recent enforcement activities have been directed towards claims made in connection with Internet-based advertising. In November 1998, for example, the FTC helped to organize an "Internet Surf Day," in which 80 public and private consumer protection organisations from 25 countries (including the U.S., Canada and Mexico) examined Internet sites to try to identify potentially false or deceptive advertising claims about the prevention, treatment or cure of six major diseases. About 1,200 sites were found to have potentially unwarranted claims, and were sent e-mail warnings by the FTC reminding them that U.S. and other countries' laws prohibit false and misleading advertising. According to the FTC, a follow-up sampling of some of these sites indicated that 28% had either modified their sites or taken them down entirely.[84]

As noted in an earlier Section, the FTC's and FDA's enforcement efforts are supplemented by the efforts of many state and local consumer affairs offices, as well

[83] An excerpt from the FDA's Regulatory Procedures Manual containing standard language for such letters is attached at annex X.
[84] A copy of the FTC e-mail notice, along with a press release describing this enforcement activity, are attached at annex XI.

as private consumer and membership-based organisations that monitor claims made about particular foods and dietary supplements.

C. LEGAL PERSONS ENTITLED TO TAKE LEGAL ACTION

Complaints may be made to either the FDA or FTC (as well as the state and local authorities and private organisations that make supplementary monitoring efforts) by any individual or organization that has reason to believe a nutrition or health claim does not comply with federal law, regulations or policy.[85]

Such complaints sometimes form the basis of enforcement proceedings by the federal regulatory agencies. This is especially true when they suggest a pattern of false or misleading claims by one or more manufacturers (which is where the FTC and FDA tend to concentrate their enforcement activities). In addition, the regulatory agencies may introduce enforcement proceedings under their own initiative. (An FTC official has estimated that about 70% of that agency's enforcement efforts are based on their own initiative, while 30% stem from consumer complaints).

The attorney general of the 50 states are also authorized to bring enforcement suits over claims made on products distributed within their jurisdiction, and many have been quite active in enforcement activities.

D. BURDEN OF PROOF

1. Burden of proof

Under the U.S. system, it is generally the party making a claim that carries the burden of proof for its validity. As explained above, for example, a manufacturer seeking prior FDA approval for a nutrition or health claim is required to submit evidence supporting the claim, including evidence that there is significant scientific agreement that the claim is well-founded. Similarly, a manufacturer seeking to make a health claim based on an authoritative statement by a federal scientific body is required to produce evidence supporting the claim, including evidence a copy of the authoritative statement and the reasons that it supports the claim being made.

In cases such as the latter, because they do not involve prior regulatory approval of a claim, the regulatory agency is given a fixed number of days to block the claim, either by issuing a regulation against it or obtaining a court order against its use. Such an action would be based upon the FDA's assessment that the necessary scientific proof had not been produced by the manufacturer. However, the burden of proof technically remains with the manufacturer to produce such evidence, even if the manufacturer might disagree with the FDA's assessment over whether the standard had been met.

[85] A copy of the FTC's model claim form, which can be accessed via their web site, is attached as annex XII.

2. Proof to be adduced

A detailed summary is given in an earlier Section of the type of proof that manufacturers must produce to support their claims and recent court rulings questioning the substantiation standard that the FDA has traditionally applied.

E. APPLICABLE PENALTIES

The range of remedies available in cases of false or misleading claims includes both criminal and civil penalties, as well as measures calling a halt to the claim in question and even providing redress to affected consumers.

Under the Federal Food, Drug and Cosmetic Act, for example, it is a criminal offense to introduce into interstate commerce any food or similar product that is misbranded; products are considered to be misbranded if their labelling or advertising is considered false or misleading.[86] Such offenses are punishable by up to one year in prison and/or a fine of $1,000 per offense, as well as the possibility of additional civil penalties. These penalties are increased for second and subsequent offenses, or if the violation was committed with an explicit intent to defraud or mislead.[87]

In addition, regulatory authorities may seek numerous other forms of redress, which include: seizure (or preventing the importation) of misbranded products, a court order forcing cessation of the claim, a court order forcing a company to compensate consumers or to disgorge profits made from the product carrying the claim, a requirement that a company having been found to have made false or misleading claims in the past post a bond in order to be able to sell that or other products in a given area. Regulators may also arrive at consent agreements with manufacturers containing one or more of these elements.

V. CASE LAW

Jurisprudence in the U.S. related to the making of nutrition and health claims has fallen generally into two categories: first, cases challenging broad aspects of the U.S. regulatory regime itself, including whether some aspects are constitutional or not, and secondly, cases involving administrative and court enforcement efforts against particular companies thought to be infringing one or more of the relevant laws.

1. Court Challenges to the Government's Regulatory Approach

A review of the recent Court of Appeal ruling is treated in an earlier Section. This calls into question whether the FDA has arrived at an adequate standard for substantiation of claims or not. It also deals with whether the FDA can prohibit claims outright (as opposed to allowing them to be made with an accompanying disclaimer statement) without violating companies' First Amendment right to free commercial speech.

[86] See Section Federal Food, Drug and Cosmetic Act, Sec. 301(a)
[87] See Section Federal Food, Drug and Cosmetic Act, Sec. 303(a)

2. Cases Involving Specific Enforcement Proceedings

As noted above, because regulatory authorities are able to settle the vast majority of questionable claims via informal proceedings, there are fewer federal court cases than might be expected, with the regulatory agencies instead relying heavily on administrative enforcement proceedings. Several such cases and administrative enforcement proceedings, which are illustrative of the federal agencies' enforcement approach, are described below.

3. FTC Administrative Enforcement Proceedings

John Sneed and Melinda Sneed d/b/a Arthritis Pain Care Center. According to the FTC, the Arthritis Pain Care Center marketed a product called CMO, which was purportedly a fatty acid derived from beef tallow, with claims that it could cure most forms of arthritis by modifying the immune system. The FTC complained that the claims were false and were not supported by authoritative statements of the National Institutes of Health, as the makers had claimed. The FTC reached a proposed settlement with the Center prohibiting these and future unsubstantiated claims or misrepresentation of scientific data.

Body Systems Technology, Inc. According to the FTC, this organisation sold shark cartilage capsules, as well as capsules and liquid containing a Peruvian plant derivative known as Cat's Claw, with claims that they provided effective treatment for cancer, HIV/AIDS and arthritis. The FTC reached a proposed settlement with the organisation under which it would cease making these or any other unsubstantiated claims, and would refund purchasers of these products within a fixed period of time.

4. Judicial Enforcement Cases

Home Shopping Network. In 1995, the FTC filed a lawsuit against the Home Shopping Network, a commercial television channel devoted to product sales. Among the products promoted by the Network were several vitamin sprays, for which the Network allegedly made claims that they could prevent the common cold and reduce the risk of infectious diseases. The Network eventually reached a settlement with the FTC in which it would refrain from making any claims for foods, dietary supplements or other products without reliable scientific evidence.[88]

VI. MEANS OF COMMUNICATION

The two main regulatory authorities in the U.S. – the FDA and the FTC – apply the same standards to nutrition and health claims regardless of the means by which they are communicated. It should be noted, however, that much of the FTC's recent enforcement activity has been directed towards the numerous claims being made via Internet marketing sites, which FTC officials indicate have largely replaced advertising materials sent via mail as their chief enforcement problem.

[88] A copy of the consent agreement is attached at annex XIII.

VII. STATISTICS ON CLAIMS

U.S. regulatory authorities indicate that they do not, as a practice, retain a regular set of statistics on the numbers of health and nutrition claims being made, how many of that number are valid (or not), or how many are the subject of complaints, either to regulators or to the private associations that assist their members in dealing with invalid claims. It is, therefore, difficult to state with any precision how many food or supplement manufacturers may currently be making such claims. However, some evidence of the FDA's thinking on these points can be gleaned from the background information it has published, including as part of related rule-making efforts.

In 1995, for example, the FDA published a survey of products stocked in supermarkets, and found that 24 out of 1,030 products contained some kind of health claim stating a relationship between a component of the product and a disease. While only a small percentage (2.3%) of the total number of products, this could comprise several hundred products when considering that a typical U.S. supermarket contains upwards of 15,000 products. Moreover, the number of such health claims is likely to have risen since 1995.

With regard to dietary supplements, the FDA has estimated that there are some 850 companies currently marketing an estimated 29,000 supplement products in the United States. Of this number, the FDA believes that most manufacturers rely (and will continue to rely) on structure/function claims rather than on other kinds of claims. Since notification procedures for structure/function claims were issued in October 1997, the FDA indicates it has received more than 3,000 notifications of manufacturers' intention to use such claims. This would suggest that more than 10% of the supplement products currently in circulation are making structure/function claims.

In contrast, the FDA has indicated that it expects only 12 supplement manufacturers per year to seek the use of health claims based on authoritative statements of federal scientific bodies, and that these 12 would file only five notifications each. As noted above, the resulting total of 60 notifications per year would be dwarfed by the number of structure/function claims being made by the supplement industry.

VIII. ANNEXES

1. *Enforcement Policy Statement on Food Advertsing*, May 1994 (Federal Trade Commission)
2. *A Food Labelling Guide*, September 1994 (Food and Drug Administration)
3. Conditions and limitations to the use of generic health claims (Food and Drug Administration)
4. *Federal Food, Drug and Cosmetic Act*,
5. *Nutrition Labeling and Education Act*
6. *Code of Federal Regulations* (excerpts)
7. *Dietary Supplement Health and Education Act*, 1994

8. *Regulations on statements made for dietary supplements concerning the effect of the product on the structure or function of the body"*, April 1998 (Food and Drugs Administration)
9. *Food labeling: use on dietary supplements of health claims based on authoritative statements*, January 1999 (Food and Drug Administration)
10. Excerpt from the FDA's Regulatory Procedures Manual
11. Copy of the Federal Trade Commission's e-mail notice to Internet sites breaking the rules
12. Copy of the Federal Trade Commission's model claim form
13. Copy of the consent agreement between home shopping network and the Federal Trade Commission.

IX. DATABASE OF CONTACTS

R. CANADA

I. EXECUTIVE ANALYSIS

A. INTRODUCTION

This study took place during an important process of reform in Canada. The Canadian authorities intend to review the regulatory framework governing claims on food within the next few months, thus showing the need for change and adaptation in this area. The reform is driven by two inter-related factors. One is the growing importance, in the eyes of Canadian consumers, of nutritional information in the observance of healthy diets. The other is the lack of such information on food labels and in advertising in comparison with the United States.

This situation is not only the result of a non-mandatory system of food labelling (compared to the mandatory American system). It also stems from the fact that the regulatory framework governing food claims is more restrictive in Canada than in the United States.

The current review is generally well received by all interested parties in Canada, including producers and manufacturers. Some of them, however, criticise the slowness of the Canadian government in carrying out changes in the legislation. It should be stressed that the process of reform is still ongoing. Consequently, the outcome remains to be determined.

B. MEMBER STATE POLICY

1. Nutritional claims

The definition of a nutrient content claim is the same as defined in Codex Alimentarius. However, this definition has no legal force in Canada since it is included in an information document with no legal value (namely the Guide to Food Labelling and Advertising). The same document defines comparative claims in a very similar way to Codex Alimentarius.

Changes in the system governing nutrient content claims have been under discussion for the last three years in Canada. Specific requirements regarding the use of nutrient content claims are spelt out in the Guide to Food Labelling and Advertising. However, Health Canada would like to regulate all nutrient content claims in the future. Food industries and manufacturers are reluctant to see the introduction of new regulatory measures: they believe that non-regulatory instruments are more flexible and, therefore, more effective. The compositional criteria for nutrient content claims are also under review. Health Canada is in the process of analysing the stakeholders' positions and, on this basis, plans to introduce new regulatory measures by the end of the year.

2. Health Claims

The legislative framework governing health claims is also in the process of being modified. Although the term health claim is not defined in Canadian legislation, a difference is made in practice between therapeutic claims, risk reduction claims and structure/function claims.[89] Therapeutic claims and risk reduction claims are currently prohibited in Canada, whereas structure/function claims are allowed under specific conditions, as in the United States. However, the Canadian government intends to introduce the ten generic health claims authorised in the United States (which are all risk-reduction claims).

In the longer term, standards of evidence and a guidance document for the submission of new risk reduction claims should be developed. Stakeholders are currently being consulted on these issues. The Food industry is satisfied with the proposed changes, as they would create "a level-playing field" with the United States in terms of marketing opportunities. Non governmental health organisations are also supporting the government's positions. Only a minority of consumer groups remain reluctant to changing the system. This is mainly due to fears of an increase in prices. They believe that the use of health claims will actually have little impact on the diet of consumers but will serve as an excuse to raise prices on the part of manufacturers.

3. Ethical Claims

In Canada, the issue of ethical claims has received little attention to date. There is no legal definition of an ethical claim and no directly relevant legislation. Some industry groups tend to explain this general lack of interest for ethical claims by the fact that they are harder to make on perishable foods than on manufactured goods.

C. VOLUNTARY CODES OF PRACTICE

In Canada, the only voluntary code of conduct on health or nutritional claims concerns claims made in advertising. The Canadian Code of Advertising standards, administered by Advertising standards Canada (a national industry association independent from the government), sets out guidelines which, in principle, are applicable to advertisements containing food claims. However, these guidelines are superceded by existing legal rules since both instruments spell out equivalent prohibitions.

The absence of voluntary codes of conduct or self-regulations for labelling claims lies in the fact that the Guide to Food Labelling and Advertising already operates. This is a non-binding document, which has been approved by representatives of the industry and the consumers during consultations with the government.

[89] The structure/function category used in the United States and Canada corresponds to the enhanced function category used in a few European countries. Structure/function claims are defined as claims which describe the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, or that characterises the documented mechanism by which a nutrient or dietary ingredient act to maintain such structure or function (US definition, taken on by the Canadian authorities).

D. VERIFICATION SYSTEMS

With regard to the issue of verification of claims, there are no general pre-clearance rules in Canada. Only broadcast advertisements are subject to a non-binding pre-clearance scheme administered by Advertising standards Canada. ACS reviews the advertising copies to ensure compliance with the Food and Drugs regulations and the Guide to Food Labelling and Advertising. In practice, all advertisements on food and beverages are submitted to pre-clearance as soon as they contain a claim. Otherwise, broadcasters refuse to broadcast them.

As far as post-clearance is concerned, this comes under the responsibility of the Canadian Food Inspection Agency (CFIA). This verification function is carried out through ad hoc and routine plant inspections. Canadian industries hardly ever break the rules. When they do, a warning letter is usually sufficient to put an end to the infringement.

In cases where a manufacturer does not follow CFIA's injunctions, the Agency can take legal action before a criminal court. There are no examples of cases that were brought to Court by CFIA.

E. MEANS OF COMMUNICATION

There is no difference between the means of communication in Canada. The standards applicable to claims made in advertisements are the same in all forms of media.

F. CONSUMER PROTECTION

The attention of all interested parties in Canada is focused on the question of consumer information. No particular remarks were made concerning consumer protection.

G. BARRIERS TO TRADE

The issue of barriers to trade appears more relevant in the context of Canada-US relations than between Canada and Europe. The United States is Canada's first trading partner and vice-versa. In principle, Canada's more restrictive framework of regulations on food claims can be considered as an impediment to American imports. However, trade issues are not at the core of the debate. Health Canada has made it clear that although it takes into account the potential economic and trade implications of regulatory decisions, the key issue is health.

H. CASE LAW

There is very little jurisprudence in Canada in this area. There are no examples of cases that were brought to Court by the Canadian Food Inspection Agency (CFIA).

I. STAKEHOLDER ANALYSIS

The outcome of the broad review of nutritional and health claims regulations in Canada remains to be seen, since no formal legislative changes have taken place at

this stage. Currently, the positions of the main stakeholders may be summarized as follows:

1. Government authorities

- The Canadian government intends to provide Canadian consumers with the nutritional information that they need to make healthy food choices. In this respect, Health Canada is planning to regulate all nutrient content claims in the future, thus taking a more regulatory approach than in the past. The current reform is also aimed at influencing manufacturers to produce more nutritious food.

- On health claims, the Canadian authorities recognise that diet may modify the risk of developing and exacerbating certain chronic diseases. They also believe that food can affect certain risk factors for disease. There is a clear will on the part of the Canadian government to model Canadian legislation on health claims on the American one. Some risk-reduction claims are likely to be authorised in Canada in the future. In the longer term, the Canadian government would like to adopt standards of evidence and a guidance document for the submission of new risk reduction claims.

- On ethical claims, the Federal authorities have no real position.

2. Consumer Organisations

- Consumer groups and non-governmental health organisations were instrumental in triggering the current review on nutritional and health claims in Canada. They believe that a revision of the compositional criteria will allow for more health claims and, thus, increase the level of information available to Canadian consumers.

- On health claims, only a minority of organisations remain reluctant to see the introduction of the US generic health claims in Canada, mainly due to fears of price increase.

3. Industry

- Industry pressures were also instrumental in triggering the current review on nutritional and health claims in Canada. The industry is favourable to the adoption of the US generic health claims in Canada, as it should create a "level playing field" with the United States. It also advocates the revision of the compositional criteria for nutrient content claims. However, it opposes an increase in the number of regulations. For the industry groups, the system should continue to be based on the Guide to Food Labelling and Advertising, which is a non-binding instrument.

- The current review is generally well received by all interested parties in Canada, including producers and manufacturers. Some of them, however, criticise the slowness of the Canadian government in carrying out changes in the legislation. It should be stressed that the process of reform is still ongoing. Consequently, the outcome remains to be determined. We believe, however, that a trend towards a more liberal system is clearly visible in Canada.

II. MEMBER STATE POLICY

A. DEFINITIONS OF CLAIMS

1. Nutritional Claims

The Canadian Food Inspection Agency's Guide to Food Labelling and Advertising defines a nutrient content claim as follows:

"*any statement or expression which describes, directly or indirectly, the level of nutrient(s) in a food."*

In addition, comparative claims are defined as:

"*claims which compare directly or indirectly the nutritional properties of two or more foods."*

a. Health Claims

The term health claim is not defined in Canadian legislation.

However, an internal working group of Health Canada (the Federal Department responsible for health policy) has identified three types of health claims:

- therapeutic claims: claims that a product can cure, treat, mitigate or prevent a disease or condition.

- risk reduction claims: claims that a product significantly alters a major risk factor or factors recognized to be involved in the development of a chronic disease or abnormal physiological condition through product use.

- structure/function claims: claims which describe the role of a nutrient or dietary ingredient intended to affect the structure or function in humans (US definition). This includes claims about the biological role of a nutrient generally recognized as an aid or factor in maintaining the functions of the body, or necessary for the maintenance of good health and normal growth and development.

Claims within each of these categories may be product specific or generic. Product specific claims are made for a single commercial product and cannot be generalised to other similar products unless acceptable supporting evidence is provided. Generic claims can be applied to any food, provided that it meets the criteria for the claim.

b. Ethical Claims

There is no legal definition of ethical or social claims in Canadian law.

B. LEGISLATION IN PLACE

Health and nutritional claims are regulated by the Food and Drugs Act and Regulations (Annex 1). The main provision consists of a general prohibition to *label, package, treat, process, sell or advertise any food in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, merit or safety* (Food and Drugs Act, section 5.1).

In addition, a Guide to Food Labelling and Advertising published by the Canadian Food Inspection Agency (CFIA) provides a summary of labelling and advertising requirements, policies and guidelines which deal with statements and claims for foods (Annex 2). The Guide is an information document based on the Food and Drugs Act and Regulations. Although it has no legal value, it helps to determine which claims are false, misleading or deceptive as defined by section 5.1 of the Food and Drugs Act. Food claims which comply with the guidelines described in the Guide are deemed to comply with the legal texts the Guide is based on.

1. Nutritional Claims

a. Nutrient content claims

Canadian legislation provides compositional criteria for nutrient content claims using terms such as: "free", "low", "lean", "extra lean", "light", "source", "good source", "high in", "more" and "reduced/less". These criteria are either spelt out in the Food and Drug Regulations or based on the general prohibition in section 5.1 of the Food and Drugs Act against false and misleading representations on labels and advertisements for food. These requirements are compiled by type of nutrients in CFIA's Guide to Food Labelling and Advertising, Sections 6.2.1 to 6.2.6.

The use of a nutrient content claim is subject to a declaration of the particular nutrient claimed in the nutrition information panel and, in the case of sodium, potassium, cholesterol and fatty acid claims, declaration of additional nutrients. These declarations must be based on a serving of a stated size of the food as sold. Specific labelling requirements exist for claims for special dietary use such as "low sodium", "low calorie" and "sugar free".

b. Comparative claims

In Canada, comparative claims may refer to positive characteristics of food - such as "contains 50% more protein than", "contains as much as" – or the potentially negative characteristics – such as "contains 20% less fat than", "reduced in", "lower in".

According to the Guide to Food Labelling and Advertising, comparative claims are potentially misleading unless they:

- involve similar foods;
- clearly identify the foods being compared and the differences between them;
- are based on differences which are both nutritionally and analytically significant; or

- are accompanied by other relevant nutrition information regarding the compared foods.

Comparative claims can, therefore, be made under the following conditions only:

- the reference food must be a similar food: the reference food must either be another brand of the same food, a different version of the same food, a substitute food or at minimum a food belonging to the same food group according to Canada's Food Guide to Healthy eating;
- the reference food and the amount of difference must be clearly identified: the claim must be accompanied by the amount of difference and the identity of the reference food. Incomplete comparisons such as "less fat" or "less salt" are considered misleading;
- the comparison is to be based on a significant difference with the reference food: differences in energy value or nutrient content should be more than 25% per serving from the reference value; and
- relevant nutrition information regarding the compared foods must be provided.

2. Health Claims

Canadian law restricts the nature and extent of health information that can be communicated on food labels and in advertising. A distinction is made between structure/function claims, on the one hand, and therapeutic claims and risk reduction claims, on the other.

a. Structure/function claims

According to the Food and Drug Regulations, some structure/function claims are permitted on foods.

The Food and Drugs Act and Regulations (Sections D.01.006 and D.02.004) authorize labelling or advertising claims concerning the action or effects of a vitamin or mineral nutrient contained in the food, such as: protein, fat, carbohydrates, sugars, sorbitol, mannitol, xylitol, starch, dietary fibers, amino-acids, linoleic acid, cis-methylene interrupted polyunsaturated acids, cis-monounsaturated fatty acids, saturated fatty acids, vitamins and mineral nutrients, listed in Tables 1 and 2 of the Food and Drugs regulations.

The following conditions apply:

- the claim may not refer directly or indirectly to the treatment, mitigation, or prevention of any disease, disorder or abnormal physical state, or symptoms of the same, nor may it refer directly or indirectly to correcting, restoring or modifying organic functions;

- the claim may not refer directly or indirectly to the treatment, prevention, or cure of diseases listed in Schedule A of the Food and Drugs Act, Section 3.1; and

- A claim may be made to the effect that the substance for which the claim is made is generally recognized as an aid in maintaining the functions of the body necessary for the maintenance of good health and normal growth and development.

  The following examples of acceptable claims are given by Health Canada: "calcium aids in the growth and maintenance of bones and teeth", "protein is needed for the maintenance and repair of body tissues"

  The following examples of unacceptable claims are given by Health Canada: "calcium fights bone disease such as osteoporosis", "protein builds muscles and makes you stronger"

- The claim triggers a declaration of the nutrient content in a food serving of stated size;

- a minimum level of nutrient is present in the food;

- The claim should not imply that consumption of the food, by itself, will have the effect attributed to the nutrient;

  The following example of an acceptable claim is given by Health Canada: "milk is an excellent source of calcium, which helps build strong bones and teeth".

  The following example of an unacceptable claim is given by Health Canada: "milk helps build strong bones and teeth".

- The following general claims are generally-recognized functions of all nutrients and are permissible: "X is a factor in the maintenance of good health", "Y is a factor in normal growth and development"

Wellness claims, such as "promotes a good night's sleep", "helps relieve fatigue", "encourages energy during the day", or other physiological states not associated with a disease, are reviewed on a case by case basis. In most cases, the use of such claims is discouraged.

b. <u>Therapeutic claims</u>

Under the Food and Drugs Act, therapeutic claims are prohibited on food products. Otherwise, these products are classified as drugs.[90] This prohibition also applies to

[90] The Food and Drugs Act defines food as *any article manufactured, sold or represented for use as food or drink for human beings, chewing gum and any ingredient that may be mixed with food for any purpose whatever*. A drug is defined as *any substance or mixture of substances manufactured, sold or represented for use in (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals; (b) restoring, correcting or modifying organic functions in human beings or animals or (c) disinfection in premises in which food is manufactured, prepared or kept.* In Canada, all drugs are submitted to pre-market approval and can be

nutraceuticals and functional foods (see *Policy paper on nutraceuticals/functional foods and Health claims on foods,* Annex 3)

The Food and Drugs Act (part I, section 3.1) prohibits the sale or advertisement to the general public of *"any food, drug, cosmetic or device to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states referred to in Schedule A"* of the Food and Drugs Act (Annex 4). This list covers a wide range of diseases, including not only many chronic diet linked diseases such as cancer, diabetes, heart disease and obesity, but also other diseases such as alcoholism, hair loss and impotence. Therapeutic health claims are, therefore, prohibited in Canada. The rationale behind this prohibition, which was introduced in Canadian legislation in 1934, is that the 46 diseases listed in Schedule A require medical diagnosis or treatment: the general public should not be self-medicating for these conditions.

c. Risk-reduction claims

Risk-reduction claims are not allowed on foods in Canada. However, a shift in policy development is taking place (see Section D.2).

3. Ethical Claims

There is no specific legislation on ethical claims in Canada. However, section 5.1 of the Food and Drugs Act on false and misleading representations on labels and advertisements applies to ethical claims.

C. EXISTING PROHIBITIONS, RESTRICTIONS AND EXEMPTIONS

1. General prohibition

Section 5.1 of the Food and Drugs Act prohibits claims which are false, misleading or deceptive and which are likely to create an erroneous impression regarding the food's character, value, quantity, composition merit or safety. This general prohibition applies to nutritional claims, health claims and ethical claims.

Specific conditions for the use of nutrient content claims and health-related claims are set out in the Guide to Nutrition Labelling and Advertising. The conditions for certain types of claims are presented below. A full list of the conditions which each type of claim must meet may be found in the Guide to Food Labelling and Advertising in Annex 2.

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sold only with a Drug Identification Number; they must also comply with testing procedures and are submitted to post-market surveillance.

2. Nutritional Claims

a. Claims regarding content

Claims on labels or in advertisements relating to the content in the food of a number of substances are subject to conditions spelt out in Sections B.01.300 to B.01.311 of the Food and Drug Regulations. These conditions vary according to the substance concerned.

For instance, claims about protein, fat, carbohydrate, sugars, sorbitol, mannitol, xylitol, starch, dietary fibre and amino acids are allowed under the condition that the content of the substance to which the claim relates is declared in grams per serving of a stated size (this does not apply to formulated liquid diets, human milk substitutes or foods represented as containing a human milk substitute). Claims that a food is low in fat or is a low-fat food are prohibited unless the food contains no more than 0.15 grams of fat per gram of dry matter and a serving of stated size of the food contains no more than 3 grams of fat (this does not apply to formulated liquid diets, human milk substitutes or foods represented as containing a human milk substitute).

b. Claims regarding energy value

Claims relating to the energy value of the food are allowed under the condition that a declaration of the energy value, preceded by the word "energy", expressed in calories and kilojoules per serving of a stated size, is made (this does not apply to formulated liquid diets, human milk substitutes or foods represented as containing a human milk substitute).

c. Claims regarding fatty acids

Claims regarding the presence in the food of a specific fatty acid other than linoleic acid, or of a specific group of fatty acids other than cis-methylene interrupted polyunsaturated fatty acids, cis-monounsaturated fatty acids and saturated fatty acids are prohibited (this does not apply to formulated liquid diets, foods represented for use in a very low-energy diet, meal replacements, nutritional supplements, human milk substitutes or foods represented as containing a human milk substitute).

3. Health Claims

a. Claims regarding the action or effects of specific substances

According to section B.01.311 of the Food and Drugs Act, claims concerning the action or effects of any of the following substances contained in the food are not allowed:

- linoleic acid
- cis-methylene interrupted polyunsaturated fatty acids
- cis-monounsaturated fatty acids
- saturated fatty acids a substance referred to in any of paragraphs B.01.300(1)(a) to (j).(2)

However, such claims may be made to the effect that the substance (in respect of which the claim is made) is generally recognized as an aid in maintaining the functions of the body necessary to the maintenance of good health and normal growth and development.

4. Ethical Claims

There is no specific restriction on ethical claims in Canada. However, ethical claims are subject to the general prohibition spelt out in Section 5.1 of the Food and Drugs Act.

D. POLICY DEVELOPMENTS AND STAKEHOLDERS' POSITIONS

Canadian policies regarding food labelling and advertising are designed to:

- protect health and safety and to prevent product misrepresentation and fraud;

- promote an informed food choice, by providing consumers with reliable and comparable information; the Canadian government is committed to developing policies that reflect current food technology and nutrition recommendations;

- support market place equity and fair competition; and

- respect obligations under international and provincial trade agreements.

The Canadian food and beverage industry, for its part, is committed to:

- maintaining truth and integrity in consumer communications;

- strive to ensure that product communications comply with the food regulations, practices and policies; and

- allow consumers to make informed choices by striving to promote messages in advertising and labelling that reflect consumer requirements for food consistent with current health, safety and nutrition recommendations; reflect current technological advancement; do not mislead the consumer; and promote fair competition in the marketplace.

All interested parties work in close partnership with the Federal government through a consultation mechanism designed to ensure that regulations and policies are responsive to stakeholders needs.

In this respect, the Canadian government has recently launched an important review process to reform the regulatory framework governing claims on food products. The first aim of this review is to give Canadians the nutritional information they need to make healthy food choices; it should also influence manufacturers to produce more nutritious foods. The second objective is to harmonize Canadian law with American legislation, whenever possible.

In preparation for the review, Health Canada is currently carrying out three separate consultations on nutrition labelling, nutrient content claims and health claims. Thus, the Canadian system of food labelling and advertising is undergoing an important reform, whose outcome will only be determined during 2000.

1. Nutritional Claims

a. Nutrient content claims review

In January 1996, Health Canada and Agriculture and Agri-Food Canada published a consultation document on nutrient content claims, which proposed that the compositional criteria for nutrient content claims be harmonized, where feasible, with those of the United States. This change was triggered by growing dissatisfaction on the part of Canadian consumers, who felt they were provided with little information compared to the American consumers and did not have the ability to make healthy food choices.

Following this first consultation, the compositional criteria for the claim "fat free" was revised in 1997. The previous definition was considered restrictive because few foods qualified for that nutrient content claim. The claim "fat free" was dealt with on a priority basis because it related to both health and trade. The economic and trade impact analysis carried out by Agriculture and Agri-Food Canada, indeed, indicated that aligning the Canadian criteria to US standards would result in increasing two-way trade between the US and Canada. Consequently, the definition for fat free was therefore changed from "not more than 0,1 grams of fat par 100 grams or 100 millilitres of food" to "less than 0,5 grams of fat per reference amount and per labelled serving of a food.

In the meantime, Health Canada has indicated its intention to regulate all nutrient content claims in the future, in order to ensure consistency in their application. Revised proposals on compositional criteria for nutrient content claims were put forward in March 1998 (Annex 5) and a second consultation of the various interested parties was held between April and June 1999.

Industries and manufacturers consider that there should be no new regulatory measures: the system should continue to be regulated under the non-binding Guide to Food Labelling and Advertising.

Stakeholders' positions are currently being considered by Health Canada and not available to the public. They will serve as a basis for regulatory measures, which Health Canada hopes to introduce by the end of 1999.

2. Health Claims

Health Canada recognises that diet may modify the risk of developing and exacerbating certain chronic diseases. It also acknowledges that individual components of food can affect certain risk factors for disease.

However, the restrictive nature of the legal instruments governing health claims is currently not in line with this global policy thinking. Consequently, Health Canada has indicated its intention to remove unduly restrictive regulatory barriers to communicate scientifically valid health information on food labels and in advertising.

In this respect, the Canadian government is considering adopting the generic health claims, which are authorized in the United States. There are currently 10 generic health claims allowed in the US, which are all risk reduction claims.[91] They could be introduced as such in Canada, but a Canadian regulatory approach is advocated in their implementation (see discussion paper: *US generic health claims in Canada*: *background and implementation issues in the Canadian context*, June 1999, annex 6)

This position is a response to industry group pressures to allow US based claims in Canada, in order to have a level playing field with the United States. Industries would like to go even further by creating a system which allows product-specific health claims. Health Canada's move also satisfies the demands of non governmental health organizations. However, there seems to be no consensus among consumers on what claims, if any, should be allowed. Some consumer organizations, although quite isolated, are reluctant to allow health claims on products because they believe it may add to cost of the product without overall health benefit to the consumer. Others advocate the use of health claims to allow Canadian consumers to make healthy food choices.

In the longer term (two to three years), Health Canada therefore intends to develop a regulatory framework to allow for new generic and product-specific risk reduction and structure/function health claims for foods. It also aims at developing Standards of Evidence and a Guidance document for submission of new generic and product-specific risk reduction claims.

In June 1999, Health Canada called on stakeholders to give their opinion on four issues that will affect the successful adoption of US generic claims in Canada:

- the appropriateness of the US general requirements for generic health claims in Canada;
- the appropriateness of the US specific requirements for generic health claims in Canada;
- Canadian format issues around generic health claims;
- Canadian credibility issues around generic health claims.

Comments will be analysed later this autumn. No position paper has been received by Health Canada to this date.

[91] The health claims allowed in the US are the following: Calcium and osteoporosis; Sodium and hypertension; Dietary fat and cancer; Dietary saturated fat and cholesterol and risk of coronary heart disease; Fruits, vegetables and grain products that contain fiber and risk of coronary heart disease; Fruits/vegetables and cancer; Folate and neural tube birth effects; Dietary sugar alcohol and dental caries; Dietary soluble fiber and coronary heart disease.

3. Ethical Claims

Canada's attention is focused away from ethical claims. They are not part of the current policy review on claims and the Canadian government has no intention to develop legislation in this field. Industry and consumer groups are not focused on ethical claims either. The main reason seems to be that it is harder to make ethical claims on foods than on other manufactured products.

E. REMARKS ABOUT BARRIERS TO TRADE AND LACK OF CONSUMER PROTECTION

While Health Canada takes into account the potential economic and trade implications of regulatory decisions, its position is that health and safety issues must take precedence. This position is consistent with the provisions of the Technical Barriers to Trade (TBT) agreements under both the WTO and NAFTA, wherein members maintain their rights to establish standards to ensure an adequate level of health protection.

III. VOLUNTARY INSTRUMENTS

A. ADVERTISING CLAIMS

Advertising standards Canada (ASC), a national industry association committed to assuring the integrity and viability of advertising, has developed and administers instruments for the self-regulation of advertising which, in principle, apply to food claims.

1. Canadian Code of Advertising Standards (Annex 7)

Section 1 of the Canadian Code of Advertising Standards states:

"advertisements must not contain inaccurate or deceptive claims, statements, illustrations or representations, either direct or implied, with regard to price, availability or performance of a product or service".

Section 8 provides:

"advertisements must not distort the true meaning of statements made by professionals or scientific authorities. Advertising claims must not imply that they have a scientific basis which they do not truly possess. Any scientific, professional or authoritative claims or statements must be applicable to the Canadian context, unless otherwise clearly stated".

In addition, the Canadian Code of Advertising Standards sets out a procedure for consumers wishing to complain to Advertising Standards Canada (ASC) that an advertisement contravenes the Code.

In theory, these provisions are applicable to advertisements containing food claims. However, they overlap with the existing legal rules, since the Food and Drugs Act

spells out equivalent prohibitions. Advertising Standards Canada therefore leaves to the Canadian Food Inspection Agency the responsibility to apply the rules. Potential complaints from consumers concerning a food claim in an advertisement would be re-directed to CFIA. This is, however, a very theoretical situation, as no individual consumer or company has ever tried to challenge a claim through ASC's complaint mechanism.

a. Advertising clearance guidelines

ASC administers a clearance system for food and beverage broadcast advertising. It is a non-mandatory mechanism set up by broadcasters and advertisers (see Section V.B).

2. Labelling claims

There are no voluntary instruments in place for self-regulation of claims on food labels. In fact, the Guide to Food Labelling and advertising replaces potential self-regulations. It already reflects the needs of industries and consumers, since it was drafted in close cooperation with all interested parties.

IV. VERIFICATION SYSTEMS

A. CRITERIA FOR SUBSTANTIATING CLAIMS

1. Nutritional claims

See Section II.B.1.

2. Health Claims

See Section II.B.2.

3. Ethical claims

There is no provision for the verification of ethical claims under Canadian law.

B. LEGAL/ADMINISTRATIVE SYSTEMS FOR VERIFYING CLAIMS

1. Pre-Clearance Rules/ Guidelines

a. Labelling claims/claims in printed advertising

In Canada, there are no pre-clearance rules or guidelines for claims on labels and claims in printed advertising.

In order to preclude potential compliance problems, which could occur without pre-market review, manufacturers may voluntarily submit their claims to the Canadian Food Inspection Agency for compliance evaluation. If the claim complies with all regulations, a "letter of no objection" is issued to the petitioner.

b. Claims in broadcast advertising

A self-regulated pre-clearance system for food claims in broadcast advertising has been set up by broadcasters and advertisers. It is administered by Advertising Standards Canada on the basis of a *"No claim" Food and Beverage Broadcast Advertising Clearance Exemption Policy Document* provided in Annex 8.

Advertising Standards Canada's Food Section staff has responsibility to review advertising copies to ensure that opinions pertaining to nutrition or composition comply with the Food and Drugs Act and Regulations and the Guide to Food Labelling and Advertising.

The following rules are applied by ACS:

A broadcast advertisement for a food advertiser or for a food product is exempt from clearance requirement if the advertisement makes no "Food and Beverage" claim in the context of the Food and Drugs act and Regulations and the Guide to Food Labelling and Advertising. In this context, "food claim" means any direct or indirect visual (including legible visuals of labels) or auditory reference with respect to a specific brand name, trade name or product/food category relating to: quality; ingredient/composition; nutrition/nutrition properties; health/safety/weight management; or production/processing. A food claim may also refer to market share claims, research and survey claims and direct or indirect comparative statements (including taste claims) regarding other foods or other establishments.

The following are examples of food claims for which clearance is required:

- specific terms, such as: fresh, improved, natural, new, pure, real/true/genuine, etc.
- descriptions relating to quality: better/best, better tasting/best tasting, finest tasting, higher/highest, larger/largest, premium, superior/top/choice, etc.
- ingredient/composition: pure, organic, pesticide free, natural, etc.
- nutrition/nutrition properties: calories/low calorie/calorie-reduced, diet/dietetic, energy, enriched, fat free/low fat/less fat, light, lean, etc.
- health/safety/weight management: brain food, choice-wise/smart, weight loss/gain, health/healthy eating, etc.
- production/processing: home-made, made by hand, stone ground, etc.

Pre-clearance of food and beverage advertising is not a legal obligation. In practice, however, broadcasters require the pre-clearance of food and beverage advertisements whenever they contain a food claim. Otherwise, they refuse to put them on the air.

2. Post-Clearance Rules/ Guidelines

a. Control of compliance

Verification of compliance of food claims with the Food and Drugs Act and Regulations and the Guide to Food Labelling and Advertising falls under the responsibility of the Canadian Food Inspection Agency (CFIA). This function is carried out through routine or ad hoc plant inspections by CFIA's regional inspectors.

Non-compliance with existing rules is rare as there is a mistaken impression in parts of the industrial sector that the guidelines provided for in the Guide to Food Labelling and Advertising have regulatory status. The policy of Health Canada's Health Protection Branch has always been to promote voluntary compliance. In case of infringement, CFIA sends a warning letter to inform the manufacturer that it contravenes the Canadian legislation.[92] The company is requested to stop making the claim and is given a deadline to regularize his situation. This procedure is brought to a successful end in most instances.

In instances where the manufacturer does not comply with CFIA's injunction, the Agency is entitled to bring the case before a criminal court. However, there are no examples of cases which were brought to court by CFIA.

C. LEGAL PERSONS ENTITLED TO TAKE LEGAL ACTION

As indicated above, CFIA is allowed to take legal action, but this instrument remains very theoretical.

Individual consumers, consumer groups and industry groups could potentially challenge a claim directly before a criminal court. However, all interested parties indicate that this is very unlikely to happen because legal action is not in the Canadian mindset. Indeed, no example of such direct action has been brought to our knowledge. In some cases, however, consumers and industries have drawn CFIA's attention on what they considered were illegal practices

D. BURDEN OF PROOF

It is the responsibility of the Federal Government to prove beyond a reasonable doubt that a person violated a specific section of the Act.

E. APPLICABLE PENALTIES

Section 31.1 of the Food and Drugs Act provides:

"Every person who contravenes any provision of the Act or Regulations, as it relates to food, is guilty of an offense and liable

> *(a) on summary conviction to a fine not exceeding $CAN 50,000* (approx. 31,600 EUR) *or to imprisonment for a term not exceeding six months or to both;*
>
> *or*
>
> *(b) on conviction by indictment to a fine not exceeding $CAN 250,000* (approx. 158,000 EUR) *or to imprisonment for a term not exceeding three years, or to both."*

[92] The manufacturer is liable for claims made on labels or in advertisements for his product. Exceptionally, the retailer can bear the responsibility if it makes a claim independently from the manufacturer (in an advertisement displayed in the store for instance).

A prosecution for a summary conviction offense under the Food and Drugs Act may be instituted at any time within two years after the time the subject matter of the prosecution becomes known to the Minister of Agriculture and Agri-Food.

This applies to the violations of Sections 3.1 and 5.1 applicable to claims. However, the Canadian government rarely prosecutes a company contravening the law in making a claim on food. CFIA tries to resolve all cases through direct dialogue with the company, aiming at voluntary withdrawal of the claim.

F. CASE LAW

Our research indicates that there have been very few challenges in court about labelling and advertising claims. Thus, there is very little jurisprudence in Canada in this area.

V. MEANS OF COMMUNICATION

In Canada, there is no difference between the standards applicable to claims made in advertisements in different forms of media.

VI. STATISTICS ON CLAIMS

There are no statistics available in Canada with regards to food claims.

VII. ANNEXES

1. Food and Drugs Act and Regulations
2. Guide to Food Labelling and Advertising (Canadian Food Inspection Agency)
3. Neutraceutical/functional foods and health claims on foods -- Policy paper (Health Canada)
4. Schedule A of the Food and Drugs Act
5. Proposed revisions to the compositional criteria for nutrient content claims (Health Canada)
6. US generic health claims in Canada: background and implementation issues in the Canadian context -- Discussion paper (Health Canada)
7. Canadian Code of Advertising Standards (Advertising Standards Canada)
8. "No Claim" food and beverage broadcast advertising clearance exemption policy document (Advertising Standards Canada)

VIII. DATABASE OF CONTACTS