ASSOCIATION OF USERS AND
DISTRIBUTORS OF AGROCHEMICALS
IN EUROPE

Paris, 8th November 2002

THE CONTRIBUTION OF AUDACE
TO
A THEMATIC STRATEGY FOR
THE SUSTAINABLE USE OF PESTICIDES

[Commission Communication of 1 July 2002 COM (2002) 349 final]

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I INTRODUCTION

The challenge agriculture must meet in the 2lst century is to feed a growing population by using sustainable farming methods. According to the established definition, this means achieving this without making difficulties for future generations to do the same.

The question is to know whether the obsession with productivity associated with the use of Plant Protection Products (PPPs) is compatible with an agricultural process that will, above all, have due regard for health and the environment.

It would be absurd to claim that a strategy for the use of pesticides will not depend on the conditions in which farmers use them.

But although a number of current agricultural practices are certainly not sustainable, they are only one of the aspects of the question relating to the sustainable use of PPPs, just as this too is but one of the aspects of the sustainability of human activities as a whole.

The nature and the use of crop protection products affect ecosystems in many different ways. The regulations governing them and their application equally determine their relative safety or toxicity in our environment.

Traditionally, the use of crop protection products is analysed in terms of efficacy and in terms of risk. The latter is the sum of the inherent **toxicity** of the product and the **exposure to it** to which the user, the consumer and the environment in general are subject.

The idea of sustainability leads directly to the need to complement these analyses with other evaluation concepts, in view of very long-term usage and the indirect toxicity that may be considered insignificant at first. The lack of an objective way of assessing the long-term impact, especially of new substances, and the gaps in the evaluation of risks associated with their use, puts a strain on the confidence that the public might have in any concept of sustainability.

The magnitude of the resources devoted by the industry and the competent Community and national authorities to the field of risk evaluation and management, in comparison to the widely dispersed population of users of PPPs, leaves no doubt as to the origin of potential failures of any strategy aimed at the concept of sustainability.

In the approach currently taken by the authorities in conjunction with the industry, they are forced into creating an ever more complex environment of standards, such that it is very risky to try to define the precise and clear boundaries between what is acceptable or sustainable and what is not, in the majority of cases.

The problem of the sustainable use of PPPs would, perhaps, benefit from being widened and tackled on the basis of a more substantial principle of "**good**". From this point of view, it is not so important to analyse compliance with the standards in each particular case, but rather to evaluate the overall direction and general orientation of all the activities involved in food production and in the use of PPPs. What sorts of agricultural food

production do the regulations encourage? What trends, what types of behaviour are they inclined to develop? And, finally, does the intrusion of the regulations and the communications of the agrochemical industry make our agriculture a sustainable agriculture?

A clear-sighted approach to the strategy to be developed to achieve the beneficial and sustainable use of PPPs will also stress the inequality of power between users and manufacturers. The latter have access to enormous knowledge and resources. In addition to their compounds, they probe, study, train or anticipate the behaviour of the user, of the final consumer and of the legislator. They refine their methods of communication, and the quite legitimate pursuit of financial results leads them to resort to techniques which are the most advantageous to them. Holding this power implies a fundamental responsibility.

This inequality of power has created a chronic situation of failure, the answer to which does not depend on the users of PPPs.

In fact, the myth of the polluting farmer, with no respect for his natural environment and unconcerned about the use of the products for which he pays so much, disguises a regulatory and industrial reality which is not moving in the direction of sustainable agriculture in many respects.

As the PPPs constitute a market in which several millions of European farmers are players, it seems to be a basic fact that the absolute necessity for their good and sustainable use relies above all other things on:

- coherent and logical regulations so that they can be understood and accepted by everyone,

- a sustainable concept for their production, presentation and marketing.

II THE REGULATIONS

1. The specific place of PPPs in the regulatory framework

It is accepted that PPPs can be regarded as having a regulatory framework **upstream** that is similar to the two other categories of products whose marketing is subject to prior authorisation, after their effects on health have been investigated, namely pharmaceutical drugs and veterinary drugs (referred to hereafter as drugs).

With regard to the PPPs, the difference lies in the fact that their marketing authorisation (MA) depends more on their effects on the environment in the sense of the ecosystems on which drugs would only have little impact.

In plain words, this means that the regulations governing PPPs impose more constraints than those concerning drugs given the gaps in Directive 91/414/EC that need to be plugged, as revealed by the Commission in its communication of 1 July 2002.

However, with regard to their prescribing and their distribution, the PPPs have no specific regulatory framework **downstream**, unlike drugs for which the doctor or veterinary practitioner must state the therapeutic recommendation on the prescription, and which must be distributed through authorised specialists.

In addition, and with regard to the extremely sensitive drugs, the patient or the stock breeder is so little affected by the regulations because their handling and their use are strictly reserved to therapists.

Patients and stock breeders cannot basically choose their medication and are not directly addressed by the communications and publicity of the manufacturers.

The farmer, on the other hand, is simultaneously the therapist, the handler and the applier of PPPs. He is directly exposed to the advertising messages of manufacturers. Although he may be assisted in his diagnosis by public services (agricultural notices from the competent authorities) or private agencies (agricultural advisers), the final choice of PPP to use always rests with him. This "self-medication" forces him to know the regulations, including their most scientific aspects, and to be a crop protection professional.

In such a situation, and when the sustainable use of drugs in the Community is the responsibility of only a few tens of thousands of doctors, veterinary practitioners and pharmacists specifically trained for this purpose and whose work is exclusively confined to this role, the sustainable use of PPPs is the responsibility of several millions of multidisciplinary farmers.

A risk management strategy will fail to meet its objectives if it does not take into account the law of large numbers, in that a technical regulation has so much less chance of being strictly complied with the larger the number of players involved in its application, and when, in addition, the majority of them are not exclusively specialised in the work regulated.

Thus the strategy concerning the sustainable use of PPPs must incorporate the possibility of mistakes in handling and use, whether these mistakes are accidental or are the result of certain individuals looking into techniques which seem to them to be more advantageous.

To a large extent, reducing this risk depends on the separation of advisory and marketing activities, as well as on regulations that are readily accessible and are understood by everyone.

2. Directive 91/414/EC

With the exception of the implementation of Community (i.e. centralised) MA procedures, we will not return to the gaps so rightly mentioned by the Commission in its communication of 1 July 2002.

2.1 Harmonisation of national regulations restricted to substances

The contradiction that exists between the free trade in agricultural products and the potential prohibition by one Member State of the use of a PPP approved in another Member State is the major cause of incomprehension with which farmers regard the regulations.

Incomprehension of this sort must not be ignored in the context of the strategy we are concerned with here because it is responsible to a large degree for the failures thwarting the sustainable use of PPPs, the first of which is illegal importation, mentioned by the Commission in its communication.

As a result, according to the defenders of national MAs granted to PPPs, one must recognise, given the legal decisions of the European Court of Justice, that this is justified because the agronomic, crop protection and environmental, especially climatic, conditions affecting the use of the product are different from State to State.
Some people add to this list the different dietary regimes of European consumers.

However, given that the MA is national and not regional, Community-wide or applicable to small fields, these differences exist just as much within the territory of a single Member State.
Moreover, with regard to which PPP, whose substance is listed in Annex 1 of the Directive, would be so specific that its use should be reasonably confined to one State, the manufacturers and the competent authorities do not have a single example.

The defence of a national MA as opposed to a Community MA rests, therefore, on no criterion of objectivity, proportionality or necessity.

On the contrary, these three criteria, elevated to the status of principles by Community regulations, support the idea of a centralised MA, given that the sustainable use of PPPs is also determined by the qualitative identity of the products placed at the disposal of farmers throughout the Community, even if the doses and conditions of use may be different on occasions within the territory of one State as much as between States.

Directive 91/414/EC specifies the essential requirements, which are themselves a reflection of the legitimate interests regarding the protection of health and of the environment, which must be fulfilled by PPPs marketed in the Community.

There are two possibilities: either the Directive is concerned with commercial products, which resolves the problem of their use by all European farmers. On this basis, the

situation comes down to complete harmonisation comprehensible to all users. It would also enable the essential requirements to be determined for the coformulants.

Or alternatively, the Directive is concerned solely with the active ingredients, and their formulation remains a matter for the judgement of each Member State. In this case, which is infinitely and pointlessly more complicated, the legal rule applicable to safeguard the use of a given PPP throughout the territory of the Community is the principle of mutual recognition. The logical consequence of this, together with the rules harmonised by the Directive, must be that any product legally marketed in one State may be transferred without impediment, because it must fulfil the same essential requirements, from all the points of view that justified such impediments in the past [1].

Nevertheless, and applying the industrial logic of the manufacturers, it remains that mutual recognition cannot apply to formulations deemed to be too different and that, therefore, the decision 3052/95/EC [1] "is just right to 'round things off', in that it is the instrument which should enable the necessary adjustments to be implemented in a regulatory system that will be deemed in future to be complete".

If the Community MA is not eventually approved, the systematic implementation of this legislative arsenal should culminate in the same result, but will take more time and more resources.

It is worth noting that the USA, which has a similar regulatory framework to that set down by Directive 91/414/EC, approves PPPs by means of a centralised procedure. Moreover, the Commission and the EPA in the United States have agreed to collaborate closely in order to define a set of common rules.

2.2 Registration of substances in Annex 1 to the Directive

The starting point for the sustainable use of PPPs is the use of those with the greatest safety.

But the only condition demanded for keeping a substance registered on the Community list arises from the good intentions of the industry, with the risk that old substances of low toxicity may be replaced by new ones with less favourable toxicological profiles.

Sustainable agriculture is a need that is a matter of public interest, and should not be hostage to the latitude granted to manufacturers to decide which substances will disappear.

To this end, the intervention of the competent authorities is highly desirable, with the objective that a new substance, if it is to meet the essential requirements of the Directive, should not be listed when an older substance meets those requirements better.

[1] Revue du Marché Unique Européen 4/1996 [Review of the Single European Market]. Eric Gippini Fournier

2.3 Data protection

Since 1993, the Directive has shown a tendency to consolidate, or even to promote, oligopolies, especially in its view of commercial secrets and the concept of data protection (Article 13) as driving factors and guarantees of its essential objectives.

Allowing it to appear that data protection is the necessary compensation or the reward to be paid to the industry so that it will evaluate the potentially hazardous aspects of its products and their impact on health and the environment, is to make public authority subject to a private interest.

The use of a PPP, which is not always merely a choice between two evils, derives from an industrial and agronomic process that creates a social cost.

Balancing interests demands that the industry which benefits from its commercial activity should compensate the society that has to meet this social cost.

In our view, maintaining the balance of interests should require that the funding of data held by an industry leader should be justified by the commercial benefit resulting from access to the market, during the period of full protection granted by the combined effects of patents and the SPCP [2].

The Directive governs the inclusion of a hazardous substance on a positive list by recognising their beneficial effects as compared with the evaluation of the risks associated with its use, and should not, as a result, determine the commercial aspect.

Whereas a patent and the SPCP give the manufacturer the protection of his invention at the same time as releasing the information, with the effect that this information, available to the largest number, gives rise to new inventions in a dynamic of progress, data protection for five redundant years offers him unlimited protection, as the manufacturer will present new inventions once the first five years have elapsed.

A situation of this sort is not sustainable in the sense that it restricts innovation relating to a given substance to a single manufacturer and that, in terms of the use of the PPP in question, the farmer no longer has a choice of the best formulation from among several specialities from different sources.

3. Intellectual Property regulations with regard to coformulants

Industrial secrecy, which mainly arises from intellectual property (IP) rights affecting business (ADPIC – TRIPS [3] agreement), allows the manufacturer to avoid revealing on the label of the PPP the complete composition of the product ... and manufacturers exploit this right unreservedly.

[2] SPCP = supplementary protection certificate for plant protection products.
[3] [TRIPS = Trade-related aspects of intellectual property rights. (French equivalent: ADPIC = Aspects des droits de la propriété intellectuelle qui touche au commerce)]

Whilst recognising in its 3rd and 4th preambles that access to information for all members of the public is appropriate in environmental matters, Article 3 of Directive 90/313/EC makes protection of the environment subordinate to IP including commercial secrecy.

The Aarhus Convention confirms this subordinate relationship.

The proposed Directive of the European Parliament and of the Council (COM/2000/0402) concerning public access to environmental information states that "access to information must be granted when the general interest is greater than the interest protected by confidentiality", but it superimposes the idea of "rejecting" a request for information and of "refusing" to comply in part or as a whole, in a similar way to the Aarhus Convention.

The right thing would be to reverse this order of subordination and to fulfil one's obligation to inform the farmer about the entire composition of PPPs for the declared objective of their sustainable use.

Given that 320,000 tonnes of active ingredients are used each year in the European Union, more than 600,000 tonnes of adjuvants, coformulants and other ingredients of PPPs are also used.

And these additional ingredients are sometimes the source of more serious toxicity than the active ingredient.

The responsibility of the farmer in relation to the use of PPPs is dependent on complete knowledge of the product he is using.

His choice of the least toxic PPP, which some might rightly wish to see elevated to the status of a fundamental principle, depends on the existence, of which he is aware, of a coformulant with a toxicological classification that does not exist in a similar PPP containing the same active ingredient.

The pressing need for the sustainable use of PPPs should not be thwarted by a right relating to commercial and industrial secrecy.

The retreat of the pharmaceutical industry in the legal proceedings in Pretoria demonstrated the limitations of reasoning associated with the TRIPS [4] agreements.

4. A regulation concerning a post-MA procedure

Given the current state of the regulations, the registration of a substance on the Community list depends on the production by the applicant of the files specified in the annexes to Directive 91/414/EC.

[4] [TRIPS = Trade-related aspects of intellectual property rights. (French equivalent: ADPIC = Aspects des droits de la propriété intellectuelle qui touche au commerce)]

The MA of PPPs is also dependent on the production by the applicant of information that will satisfy the requirements of Member States.

In such circumstances, it is evident that, however exhaustive the studies demanded may be, they are carried out by the industry whose inclination is not to present its substances and PPPs in the most negative light, for all that.

In addition, however many laboratory tests and field trials are conducted, they remain very far from the conditions of widespread use when the product is launched onto the market.

The possibility of taking into consideration the observations of operators in the field, after the MA has been granted, is undoubtedly something desired by the Community and national authorities, but has not been formalised in any specific regulatory text.

It follows that, ultimately, the discovery of unusual characteristics of a PPP observed by users after prolonged use and/or use in special conditions, is rarely taken into consideration within a reasonable timescale.

With the objective of the sustainable use of PPPs, the regulatory framework must include a text that allows for all operators in the field to contribute observations and that applies in particular to the essential requirements below.

4.1 The limitations of the MA

Too frequently, after it is innocently and misleadingly announced, the MA is perceived by the farmer as being an absolute guarantee of the safety of a product.

It is right to dispel this illusion and to return to the hard reality that the MA is only the result of the balancing of positive and adverse effects of a PPP.

Without fear of contradicting what has been affirmed in the past, all users in the Community must be made aware of this reality, which both makes it their responsibility to defer a positive assessment until the product has been handled and applied and, in these circumstances, gives them the power to dispute the justification for this if necessary.

4.2 Clear recognition of the adverse effects

With the aim that nobody should be unaware of the limitations of the MA, the adverse effects should be at least as obvious from the information given to the user as the positive effects.

Although there is no doubt about the usefulness of toxicity and ecotoxicity symbols for this purpose, it is no less true that the announcements by manufacturers still basically eulogise the positive effects and completely disguise the adverse effects to the point that the risk symbols are deprived of their effectiveness.

In addition to rectifying these announcements by the leaders of the industry, permanent information on all the adverse effects observed during the MA procedure must be kept available to the public.

4.3 Revision of the MA following observations relevant to use

Any adverse or positive effect found when the product is handled or applied, which would not be stated in the information relating to the MA must be brought to the attention of the competent authorities, and they must be required to give the informant a substantiated response irrespective of his status.

If, after examining the observations within a reasonable period, the newly observed negative or positive effect is confirmed, the immediate revision of the PMA should not take account of the rights granted to the manufacturer by the initial MA.

4.4 Suspension of the MA following an incident during use

After having used a PPP under the conditions prescribed by the manufacturer, the farmer too frequently encounters incidents in the crop or even physical problems occurring when handling the product.
Too often such reports develop into legal proceedings subject to the judgement of lawyers, without the competent authority responsible for the MA even being notified of the incident or, if it is, it does not take the appropriate measures while it waits for the legal decision to be arrived at.
And this decision often does not arrive until several years after the manufacturer has immediately disclaimed responsibility on the primary grounds that the MA was obtained in accordance with the regulations.

The administrative authority must be independent of the legal authority. The procedural rules must require that the administrative authority is informed first of all of the precise conditions under which the incident occurred. If, after making its own expert assessment, the competent authority considers that there is a particular risk of the incident recurring, it must suspend the MA for some or for all of the uses or conditions of handling for which the authorisation was initially granted.

This principle, more generally called the precautionary principle, is singularly lacking in current thinking, in which there is a reluctance on the part of the competent authority to carry out a re-examination of its first decision, and of firm opposition on the part of the manufacturer, who cannot readily understand its MA being questioned again.

4.5. Immediate and transparent reaction to the occurrence of unintended effects

Unlike the incidents referred to above, unintended effects of PPPs may be observed not only by farmers but by any member of the public, starting, for example, with the trades peripheral to agriculture, the food industry and the medical professions.

Given the current situation, there is, unfortunately, no need to provide evidence of the extreme difficulty of determining the causes and the answers to unintended effects associated with the use of PPPs.

Proof is given by the fact that, after having been submitted to the national administrative, political and legal authorities, some ten year old files may still remain unresolved to this day, and plagued with controversy or, at least, disputed by dissatisfied victims.

The inability of countries to resolve on their own the matter of unintended effects is especially, and often, the consequence of the multinational character of the manufacturer of the PPP or PPPs concerned, in that the manufacturer routinely claims that his products could not be responsible as legal proceedings have not occurred in other countries.

The primary answer to this, to transfer on a routine basis such files to the competent Community authority, is an obvious necessity.

As many of the unintended effects are such as to be detrimental to the entire population, it is important that they should be investigated with the greatest transparency so that precautionary measures can be taken by each category of professional in society, so that the sets of indicators enabling causes to be determined will emerge.

Finally, reaction to an unintended effect must be all the more immediate if its resolution, in part or as a whole, is easy to implement. For example, it is clear that with regard to the presence of PPPs in the air, prohibition of aerial application throughout the territory of the Community will contribute to resolving the problem.

4.6 Applicable doses specified by the MA in relation to the reality of use

The applicable dose specified by the MA is the smallest dose that will guarantee the best efficacy in all circumstances encountered. This means that if a PPP achieves good protection in a given dose in 90 % of situations, but that in the most problematical situations a higher dose is necessary, it is the latter which is taken to be the minimum effective dose and is the dose authorised.

In principle, a product cannot be used or recommended except under the conditions described in the MA, and it is, therefore, theoretically prohibited to apply or to recommend a lower dose than that authorised.

Fortunately, observations, combined with a touch of indiscipline among some farmers, have shown that the authorised doses may often be considerably reduced, with no effect on the biological result.

This fact, known and accepted by the competent national authorities in relation to very widely distributed products, has not generally resulted in the logical conclusion of a programme for the revision of authorised doses in relation to the reality of use.

Given that the sustainable use of PPPs is also determined by the quantities used, a revision programme of this sort is needed.

5. Control of the implementation of up-to-date technology

No concept of industrial or intellectual property (IP) should overlook the necessity for safeguarding and promoting the public interest and merely serve a private interest.

Accordingly, it is not acceptable that known, up-to-date technology should not be exploited, if it would, for example, enable a PPP to be given a less toxic composition than that initially marketed, or to replace a formulation with a less aggressive one.

Such situations exist. They arise from an industrial logic consisting in the patent protection of a manufacturing process which is intended, for example, to purify a substance of its toxic impurities, and not to make use of the patented process as long as the specific interest of the inventor does not require it.

Manufacturing products in formulations that have proved to be aggressive, such as liquids, when they could benefit from a formulation that has greater regard for health and the environment, such as granules or micro-granules, also arises from this industrial logic.

Although, in this second example, the competent authorities must have the power to refuse an MA for a formulation that poses more risks, it would be worthwhile setting up a unit composed of scrutinisers of agrochemical inventions for the situation of unexploited patents. It should have the authority to force the inventor to implement the latest technology or, failing that, to transfer its implementation to another manufacturer by means of a compulsory licence.

6. Control of PPPs marketed by companies

If the need for control over the uses of PPPs is accepted unanimously, the need for regular checks, aimed at establishing that PPPs on the market comply with their MA, should be welcomed in the same way.

These checks must be transparent and their results published, both for use and for manufacture.

III A SUSTAINABLE CONCEPT FOR THE PRODUCTION, PRESENTATION AND MARKETING OF PPPs

1. The place and the role of industry in the strategy

Alongside the regulations, the implementation of tools specific to the sustainable use of PPPs depends on the objective, rational and sincere will of the agrochemical industry, so that progress towards ethical improvement in industrial and commercial practices does not result solely from external pressures, or from the unease manufacturers have for their brand image when faced with public opinion that is increasingly hostile to their activities.

For the leading player in the sector, it is less a matter of acquiring the know-how and looking knowledgeable about sustainable agriculture, and appropriating the idea and the initiatives, than of participating actively in solving his own past failures.

In plain words, it is a matter of defining a sustainable development strategy with the aim of setting agriculture on a genuine path to progress, by each player correcting in-house the factors which have thwarted its realisation hitherto.

The authorities made responsible by public and political powers [5] for defining such a strategy express a clear opinion on the basis of this evidence that *"genuine environmental management is and will remain mainly the task of farmers, whereas image promotion is the privilege of other players"*, that *"there is a risk of those who are experts in marketing unwarrantedly appropriating the fruits of farmers' expertise"* and that *"as the environment is a public asset, such appropriation is not legitimate"*.

If *"one should not take unfair advantage of our fellow citizens,*

if *on the grounds of professional ethics, one should promote only the genuine aspects of rational agriculture, that is to say, its genuine concern for the conservation of the environment,*

if *there should be no commercial out-bidding in matters of health, and*

if, *due to the omnipotence of image, one should not allow a seductive image to replace the reality of the environment",*

then the sustainable use of PPPs will benefit from its strategy being dependant as little as possible on industrial and commercial interests and, at the very least, appear as it really is in the eyes of the public.

[5] President of the General Council of the National Institute of Agronomy (INA), former President of the National Institute of Agronomic Research (INRA), Guy Paillotin is the author of a report on rational agriculture in France.

2. Self-regulation of the industry

The manufacturers of PPPs and the organisations to which they belong have striven to draw up rules for self-regulation, generally announced to the public in the form of codes of conduct, drawing their inspiration from the "Responsible Care" programme implemented in Canada in 1985 by the chemical industry.

Although these rules, most advisedly called "soft law", are one of the communications privileges of the agrochemical industry, they in no way serve the strategy of sustainable use of PPPs, at least in the present state of their development. What is worse, whereas the strategy has great need of a public opinion that no longer holds a disastrous view of agriculture, they do it a disservice in that the public merely sees in them hypocrisy to fulfil their own interests.

In the words of a study conducted at the request of the European Commission DG SANCO in January 2001 [6], the aim of the various self-regulation initiatives is clear: it is to forestall possible legislation in order to demonstrate its uselessness better, and codes of conduct are drawn up to enhance the image of a sector in which questionable or fraudulent practices have developed. (p. 141)

The practice of self-regulation most often proves disappointing as it is limited to a list of good intentions. (p.37)
Soft law seems inappropriate for matters associated with the safety and health of consumers, in the almost unanimous opinion of experts and specialists, as they should be governed by standards laid down by the state. (p.36)

And without being experts in the subject, the public, including farmers, naturally and instinctively share this point of view.

As these standards have no legal status and are prescribed by manufacturers on their own initiative, our intent here is not to prohibit their existence, with impunity, but to express the wish, either that the public authorities announce widely that they distance themselves from these standards, or alternatively that the agrochemical industry see to it that its standards no longer exist without transparency and without the capability of being monitored and approved, especially on the initiative of other professionals in the sector and consumers.

In the present situation, federations or associations of manufacturers responsible specifically for the implementation of codes of conduct do not admit any representation by a third party that would tend to demonstrate the existence of a violation, on the grounds that only the member involved can be concerned and that it is not within the remit of a trade organisation to intervene, and still less to punish, if the need should arise.

[6] LEX FORI – Best practice in making use of "soft" law and its application to consumers within the European Union.

In the absence of machinery for imposing penalties and for making an effective claim, the public cannot avoid lacking confidence in soft law.

3. Production

3.1. Production intended for Member States

Within a short time, the industry's anticipation of the proposed regulations set out above should culminate in what needs to be implemented:

- formulations of PPPs that are not made artificially different between Member States and objectively fulfil the essential requirements of the protection of health and of the environment for the same use throughout the Community.
- State of the art technology which will best satisfy the requirements irrespective of any consideration of industrial or commercial interest.

With the objective of maintaining the diversity of agricultural production, it is not acceptable that the disappearance of substances, or the lack of economic value which is the argument against a minor use, in the case of PPPs whose active ingredients are or will be registered on the Community list, leaves crops without agrochemical protection.

A situation of this sort is an incitement to farmers to use an unauthorised speciality experimentally and will potentially run counter to sustainable use.

However, in view of the likely impossibility of the industry achieving a return on the investment represented by the costs of studies demanded by Directive 91/414/EC, the manufacturers should be in a position to put forward a cut-down procedure specific to minor uses and which would not conflict with the essential requirements.

3.2. Production in or intended for developing countries (DC)

A strategy for the sustainable use of PPPs should not be confined to the territory of the Community.

Even though the authority of the EU in relation to practices in third countries is moderate, in spite of its influence within international organisations (UN - FAO - WTO etc.), it is worth mentioning that almost 80 % of world agrochemical production comes from European companies.

The relocation of more seriously polluting production to countries that are less demanding in terms of health and the environment must be included in the strategy in question, through the desire of the industry to base its activities on an ethic with an international relevance and dimension, and through the implementation of instruments of control that will enable the reality to be verified.

With the same objective, PPPs strictly prohibited in the Community, on the grounds that they are fundamentally hazardous to health and the environment, must also be prohibited from being produced in or for third countries, especially DCs.

This should happen irrespective of the principle of prior consent established by the PIC procedure, whose inconsistency with the protection of European consumers, faced with the globalisation of trade in agricultural products and with the universal dimension of environmental protection, is evident.

Finally, the DCs still hold large stocks of expired products and/or extremely hazardous products, such as the persistent organic pollutants (POP), and with the inability to ensure their destruction.

It is highly desirable that their manufacturers should accept the proposal of the FAO aimed at their participation in the elimination of these products, as part of a sustainable strategy.

4. Presentation

4.1 Risk phrases and symbols

The proposed regulations described above, relating to the disclosure of the complete composition of the PPP, together with a clear acknowledgement of its adverse effects, in no way replace the obligations already laid down in the regulations relating to a full, clear and legible presentation of the risk phrases and symbols.

The practice of burying them in a dense text in smaller letters than those that set out the benefits of the product has the effect of disguising their importance and diminishing their effectiveness, to the point that they are not read by the user.

4.2 Tank Mixtures

The advice on the use of several PPPs mixed together at the time of use must be accompanied by the official authorisation relating to it.

4.3 "Green marketing"

The practice of "green marketing" consists of praising the safety of a product by the use of promotional images, statements on the label and commercial names that are exaggeratedly flattering, or that compare the effects of the PPP with those of substances currently used in the daily life of consumers.

An archetypal example of this practice might be promoting a PPP using a picture on the pack of children happy to romp in a field after the application of a product, intending to prove its very great regard for health and the environment and its complete safety. Another is to use a brand name prefixed by the word "BIO", and by comparing its minor effects in pictures or words, with the major effects of cooking salt, baby shampoo or Vitamin A.

In the words of Directive 2001/59/EC *" ... indications such as 'non-toxic', 'non-harmful', 'non-polluting', 'ecological'* ***or any other statement*** *indicating that the substance or preparation is not dangerous or likely to lead to underestimation of the dangers of the substance or preparation in question shall not appear on the label or packaging of substances or preparations subject to this Directive or to Directive 1999/45/EC".*

"Green marketing" does not actually have a place in a strategy for the sustainable use of PPPs and it could be a long time before the industry drops the practice, unless they feel compelled to comply with the existing regulatory framework.

It should be stressed that some of these larger manufacturers gave a commitment to the Ministry of Justice in the USA to cease this practice in July 1998, and that, remarkably, their practices in the territory of the Community have not been amended in spite of that in the past four years.

4.4 Advertising

The effect sought by advertising is to prompt the consumer or the user to consume or to use more of the product advertised.
It is precisely for this reason that advertising of pharmaceutical specialities is very strictly regulated and very sensibly supervised and restricted.

The quantitative significance of advertising in relation to PPPs is that its effect of prompting the farmer to use them more must be of even greater significance because it is inconceivable that the industry would allocate such a large budget without obtaining a return on its investment.

Such a situation is obviously not sustainable.

It cannot be disputed that it runs contrary to the proposal of the Commission which consists of encouraging the move towards agricultural practices using limited (or zero) quantities of PPPs.

Although the endeavour to remove the right of manufacturers to promote their products may not be realistic, and moreover not generally desirable, the endeavour to transform advertising space into communications space, aimed, for example, at describing the product with all its effects - both positive and negative – by stressing as necessary the improvement of the latter as compared with the range of existing products for the same indications, would eliminate any contradiction with sustainable use.

4.5 The packaging of PPPs

Some products are packaged in containers that provide enough for several tens of hectares, or even sometimes for over 100 hectares.

As far as the industry is concerned, these large packs are not generally an economy but the farmer may obtain a substantial price advantage from buying them.

Although containers of this sort do, after all, offer an advantage in terms of their disposal, the question of their sustainability arises in that they are an invitation to use them over a larger area than necessary, and that the difficulty associated with this handling is sometimes the cause of accidents or of mistakes in estimating the dose authorised by the regulations.

5. Marketing

The industry has an obligation to look ahead to the use of PPPs in planning its production.

The combination of stock requirements and very early commercial positioning to avoid losing market share to the competition prompts manufacturers to appeal to distributors during autumn-winter, known as the "off season" for crop protection products.

For the same reasons, distributors appeal to their farming customers in the same way.

These appeals are justified by means of preferential trading conditions based on price reductions referred to as "from stock", "off season" and "advance buying".

With the aim of gaining greater market share, the manufacturer helps its distributors and ensures the effective promotion of its products where it is used, that is to say direct to the farmer.

This strategy is also accompanied by commercial incentives applying a second category of price reductions or rebates called "positioning", "market share", "commercial policy compliance", "campaign", "trade", "rational", "progressive", or "end of campaign" reductions, among other reductions known as "pallet" or "lorry-load" for large delivery volumes.

Traditionally, farmers, and therefore their distributors, have paid up very late for PPPs, generally after they have received the first payments on account for their harvest.
Tired of supporting this funding, the industry has a third category of reductions known as "advance payments".

The final category in this array of pricing conditions is the "budget" granted to distributors provided they have satisfied various other requirements, such as promoting a programme of crop treatments, for example, incorporating, either exclusively or as exclusively as possible, the PPPs from that manufacturer's product range.

With the same objective, and in addition to the "budget", the industry follows a strategy of making its trading conditions dependent on the purchase of several products without regard to whether they complement each other in agronomic terms. In this case, two specialities are offered in a multi-pack and it is not possible to buy one without the other.

The majority of these reductions, rebates and budgets are granted in the form of "margin arrears" at the end of the agricultural campaign.

A situation such as this is obviously not aimed at restricting the marketing of PPPs and therefore their use.

"Rational" and appropriate use according to the actual health of crops observed throughout the growing cycle of crops is thwarted by the farmer's inclination to use the products that he has bought in advance and which he holds in stock.
The inclination to use PPPs as a routine preventive measure is also widely popular.

Although it would be too much to hope for a distribution system comparable to that for fixed-rate products with refunds assured by the State, a complete change in the commercial logic of the manufacturers of PPPs is extremely desirable.

IV CONCLUSIONS

Although this communication tends to place the responsibility for the sustainable use of PPPs equally on the regulations and the agrochemical industry, it is not intended to be an argument against these two primary players in the crop protection sector.

On the contrary, it does seek to refute the consensus established in the course of seminars and announcements, which exclusively places the responsibility on the farmer whenever the harmful effects of agrochemicals have to be acknowledged.

Although it clashes with the demagogic speeches for the benefit a public opinion so readily convinced that the image of a sprayer in action is inseparable from the farmer, it does not intend to gloss over the problems posed by negligent or fraudulent use.

However, as an example, the readiness to attribute the failure of a play to the actor who has been denied the opportunity of even reading his part in advance, can be applied equally to the case of the user denied the knowledge of the complete composition of a dangerous product, but nevertheless held responsible for all the dangers associated with its use.

In the light of this, AUDACE concurs with the majority of the proposals set out in the Commission communication of 1 July 2002, but not with three of them.

The first relates to that other consensus, not shared by the agrochemical industry, that organic farming could be the solution for sustainable agriculture. Although its promotion

by the public authorities tends to ease the pressure of public opinion, that form of agriculture described as obsessed with productivity nevertheless feeds the greater part of the population at acceptable cost and in an acceptable quality. Hastily and readily resorting to this method of alleviating popular anxiety springs much more from an idealistic attitude than from the objective possibility of sustainable development. It is indeed difficult to accept that the so-called productivity-obsessed sector of agriculture would bear the considerable cost of evaluating substances and the practices associated with them, if "organic" production, that incorporates some of them in their specifications, alone derived value from them.

The second relates to the special levies on PPPs which must be acknowledged to be detrimental to the idea that the most dangerous and polluting products should not be authorised. Although the special levies remain socially, economically and, above all, politically acceptable, their collection and their intended purpose should still correspond to the objective for which they were introduced.

But farmers do not notice the effect they have, because they are buried in the price of the product and therefore do not appear separately on purchase invoices, and when their application, basically intended to cover the external costs of PPPs, lacks transparency to say the least, when it is not allocated to Social Security coffers by some Member States.

The third concerns the levels of value added tax affecting PPPs. Although the harmonisation of VAT between the Member States is desirable in any event, increasing it would either be pointless in the case of farmers who are opting for the cash method in increasing numbers, or it would be discriminatory against those who persist with the all-in price method.

Farmers are not the only users of PPPs.

Local communities, highways departments and private individuals make use of them to a greater extent than agricultural professionals in terms of the areas involved.

Some initiatives aimed at limiting these uses, especially by private gardeners, to specialities which are non-toxic are worth extending throughout the Community.

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Farming is an inexact science subject to variations and imponderables known in no other human activity. It has fed human beings from its earliest days and will fortunately remain for a long time to come the essential means for their survival.

In this, farmers are the essential players; the great majority of them are excellent, and there is a great need for their skill to be recognised.

To this end, **fair** control over agricultural production, so that the failures of some of them are not prejudicial to this majority, is an urgent necessity.

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