Association of Users and Distributors of AgroChemicals in Europe

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A Strong Generic Competition for a Sustainable Agriculture and an Innovative Dominant Industry

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January 25th of this year, experts Alleweldt, de Borchgrave and Olivier presented under the aegis of Directorate General SANCO an impact assessment report in relation to the planned amendments of directive 91 / 414 / EEC.

No preliminary written information relating to this study, and no handouts at the conclusion of the presentation were made available.

It is constant that our active participation, although sought, in the process of revision of directive 91 / 414 / EEC since Corfu in 2002 has had only little effect on the reasoning of the Commission which clearly appears to oppose any notion of objective revision.

This reasoning of the commission leads to consider questions that are more relevant to intellectual property rights and competition issues than to the essential requirements.

In this situation, two camps oppose each other.

On the one hand, between a centralized process for the evaluation of commercial products and a decentralized process at the level of every member State or at the level of geographic zones bringing together partly or in totality several member states.

For the first one, what is at stake is the implementation of a perfectly harmonised regulation for the whole of the European single market in which no objective difference would come to oppose this perfect and total harmonisation.

For the second, agronomic, climatic, pedological, etc. differences would come to justify the necessity for a decentralised procedure.

On the other hand, on the existence of the protection of data and the duration of its exclusive use.

These two major oppositions should, in fact, find consensus through consideration of the aims and objectives of the directive, which is to protect the essential requirements the necessity of which is not disputed by any one.

In the same objective, and also since 2002, Directorate General Environment leads a reflection on the subject of a thematic strategy relating to the sustainable use of PPP in which AUDACE participated by a document of 22 pages on November 08th, 2002.

Although this communication tends to place the responsibility for the sustainable use of PPP 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.

That is why the 25 dysfunctions brought to light in this communication find their place at the centre of the reasoning that should be held by DG SANCO before proposing to the Council amendments to the regulation. The aforementioned communication is always available in five languages on the Web site www.audace.org and we shall not thus reproduce it here.

A regulation rightly criticized

The Commission points to the performance of the regulatory process by the fact notably that it would have led to eliminating more than 400 substances from the community market when these withdrawals result nearly exclusively from the industry's decision not to « invest » in the risk evaluation relating to these substances.

Nothing indicates that the alternatives to these withdrawn substances are more favourable to public health and the environment. It is a fact however that they are more profitable for the industry and thus more expensive for the user who cannot pass on this additional cost to the consumer.

REACH and directive 91/414/EEC

The communications of France, Germany and the United Kingdom coming to the support of the dominant industry on the propositions to regulate chemical substances illustrate perfectly the ambiguity of a regulation which claims nevertheless to be exclusively dedicated to the protection of public health and the environment.

From the moment that this regulation would no longer further fulfil this other objective, that is the commercial protection of the industry, it is perceived as an unbearable threat to the extent that State leaders themselves drop their reserve and take side publicly against the regulation.

And it is not without cynicism that the dominant industry wonders about the impact of the regulatory project REACH on the good health of small and medium-sized companies (SMF) while since 1991 it refuses to see the impact that directive 91/414/EEC has effectively on an independent generic industry.

But it is true that the directive of 1991 contains in its articles 13 and 14 the protection of data and that REACH, still a draft, does not make provisions for such « compensation ».

Of the failure of a regulation

Three major observations are obvious :

- A dying generic industry tries in vain to speak up.
- Consumers' anxiety, which is more and more distinct, thwarts the idea according to which the process of evaluation guarantees objectively the safety of agricultural produce.
- the users, farmers, realise that the directive of 1991 amounts exclusively to a documentary inventory of studies which is totally disconnected from the production and from the marketing of products containing the evaluated substances. It is a fact that no control at present looks for nor can put in evidence that substances brought on the market really originate from processes of synthesis examined within the framework of the community evaluation.

Return on … investment

Within a decade, the dominant industry has transformed itself from a processing industry into a service industry which processes only paper to constitute files. The production, (and the industry makes no secret of it), is partially or totally delocalised. It has been reduced to the role of a « trader » that trades products that are custom manufactured by producers in India or China. These producers have no chance of direct access to finished products under marketing authorisation (MA) and to profitable markets.

In this context, the confidentiality of the data on the characterisation and the quantification of the impurities resulting from a precise process of synthesis as well as all the studies of impact of a substance on public health and the environment amounts more to a blind licence disconnected from the real conditions of marketing than to a notion of equity towards the industry which financed these studies.

The justifications for an exclusive use of the data

1991 is not 'year one' from which the industry has had to produce the data relating to the impact of its products on public health and the environment.

Perfecting the evaluations performed earlier by the competent authorities of every member State cannot justify any compensation especially when it amounts to reinstating fallen patents.

This notion, established by articles 13 and 14 of the directive, cannot even be inferred from the ADPIC agreements. The question arises thus, why a reward would come over and above the intellectual property rights (I.P.) internationally recognised on the grounds that the industry agrees to this complete review that is an improvement of the protection of the essential requirements.

Nor do the main rules framing I.P. within the European Union provide for this notion including when, and lastly, the regime for SCPP[1] was introduced to compensate for the delay resulting from the application for the MA.

[1] Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products (OJ 1996 L 198, p. 30).

Equity, for whom and according to what criteria

The users and consumers would be the main beneficiaries of the costs paid by the industry to perfect the evaluation of risks. The users, because this improvement would upgrade their production; and the consumers because they would benefit from healthier food.

And industry ?

Would it not already have benefited from the exclusivity conferred by patents and further extended by the SCPP, not to mention the synergic effects of multiple process patents which perpetuate the protection[2] ?

The exclusivity of data comes to increase over and above the profits already made and affect directly the prices paid by users without any justification.

Incidentally, from this arises a surprising internal distortion of competition within the dominant industry between the 'old' substances, which regain protection and 'new' substances still patented, which do not benefit from supplementary protection since their evaluation occurs during the lifetime of the basic patent.

Clearly it is more advantageous to review an 'old' substance than to evaluate a 'new' one.

Henceforth, the protection of data does not promote innovation. And, this, even less so that contrary to patent protection, it does not allow public access to relevant information and suppresses benefits from progress resulting from shared knowledge.

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So that the innovative industry innovates in the interest of health and the environment

Under a permanent monopoly, manufacturers have never seemed focused on innovation.

It is of course faced with the threats from generics and with the aim of blocking them that better product formulations appear just before patents are due to run out.

Suddenly, the latter are more suited to meet essential requirements, and are also aimed at blocking access to the market for generics that are merely a copy the formulation of the old patented speciality.

The same applies to innovation in terms of active substances, which is rarely seen while a patent is still alive.

Hindering access to market for generics amounts to undermining any technological progress liable to improve chemical compositions and/or PPP formulations with a view to safeguarding public health and the environment.

This stagnation is all the more harmful, given that innovation can help eliminate the most harmful substances.

[2] « evergreening » coins the concept of lasting protection in relation to those perennials that keep leaves in winter.

Generics stimulate innovation.

By hindering the preservation or the arrival of generics, the protection of data hinders innovation and comes to oppose the essential objectives aimed by the directive.

For a review that does not preclude plant diversity

Practically monopolised inclusions of substances in Annexe 1 of Directive 91/414 deprived the market of specialities whose effects on health and the environment were considered acceptable while perpetuating others much more open to discussion.

But there is another, equally damaging effect such inclusions have: they mean discontinuing substances notifiers consider uninteresting in terms of profitability, which deprives some minor crops of any phytosanitary protection whatsoever.

For generics, profitability criteria are different.

This is why a strong generic industry is essential, and is consistent with a risk management strategy that includes preserving the diversity of plant production.

Precisely the same applies to minor uses, for which efforts to obtain extended marketing authorisation are not something the dominant companies are renowned for.

Besides, the attraction of novelty combined with the effects of advertising hype that accompany new speciality launches leads to their virtual hegemony and to resistance phenomena from the parasites they fight, increasingly hard, close and frequent.

By way of example, the arrival en masse of strobilurines has, in less than five years, shown how essential the old triazoles were.

Here, once again, the existence of a generic industry strong enough to keep old specialities on the market, which the major companies have abandoned in favour of new ones, arises out of a necessity, the agricultural relevance of which should be taken into account.

For an objective re-evaluation exempt from conflicts of interests.

An independent re-evaluation financed a priori by authorities is the guarantee of a harmonised regulation, commercially neutral and consistent with the rules of the single market.

The transfer, with hindsight, of controllable and containable costs by the public authority to, notably, the holders of MA has to take into account that the re-evaluation serves exclusively the public interest.

In this way, the costs incurred for reviewed substances not complying with new requirements must, as it is very often the case in other sectors, be borne by the community.
For example, did the producers of asbestos finance the studies leading eventually to the ban of this substance?

Besides, an independent review ought to initiate the re-evaluation of substances removed from the European market for the sole reason that they were not fully supported by at least one notifier.

For a PPP regulation consistent with those of other regulated products.

It is a fact that the marketing of PPP and medicines involve comparable concerns and interests[3].

It is a fact that directives aiming at the harmonisation of procedures for evaluating medicinal products provide for the centralized MA and make it compulsory in some cases.

It is a fact that professionals of agriculture understand less and less why a PPP not authorised in a member state can be used in another one when the agricultural produce resulting from its use moves freely within the European single market.

The inconsistency of directive 91/414/EEC with these three certainties is no longer bearable.

It is all the less bearable as the procedure for mutual recognition does not work or so badly that it became unacceptable.

The centralised MA necessarily must become the resulting consequence of the re-evaluation of the 'old' substances and the evaluation of the new ones.

We believe that no exception would resist this resulting consequence. If it were not the case, the motives for which a PPP could not benefit from the centralised MA would have to be clearly and publicly stated.

Thus, and indeed beyond differences of opinion and corporatist interests, the revision of directive 91/414/EEC has to exclude the protection of data and include the notion of centralised MA if only not to be inconsistent with the objectives it sets and with the community provisions of which it is an integral part.

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[3] ECJ : judgment of 14 July 2005, case C-114/04 – point 24