

THE EU REVIEW PROGRAMME

The European Crop Protection Association (ECPA)¹ presents its view on the July 2001 Commission Report to the European Parliament and the Council on the EU Review Programme under Directive 91/414/EEC

Introduction

In July 2001 the EU Commission will report to the European Parliament and Council on the progress of the Review Programme for existing active substances in crop protection products (CPPs) under Directive 91/414/EEC. This Paper explains the reasons behind the introduction of the Review Programme ten years ago in 1991, its current status, and the crop protection industry's position on its future.

In order to set up a harmonised framework for the regulation of CPPs in the European Union, Council Directive 91/414/EEC of July 15, 1991 concerning the placing of plant protection products on the market was adopted and implemented in all Member States. This Directive and its implementing instruments provide the basis for the harmonisation of registration procedures and regulatory decisions. One of the basic principles of the Directive is to establish a positive Community list (Annex I to the Directive) of active substances that are acceptable to the environment, human and animal health and can be used in CPPs.

The Review Programme was given an ambitious target of 12 years to complete the evaluation of over 800 existing active substances. The 12 year period expires in July 2003. Experience of the Review Programme has shown that it is impossible to evaluate all these substances in this timeframe. In 1989, at the time of the development of Directive 91/414/EEC, the crop protection industry issued a Position Paper stating:

"The enormity of completing such a Review Programme within this time period (12 years) is self evident. Indeed the industry would anticipate that even allowing for the maximum use of appropriate resources available in Member States, the stated objective is unrealistic." Experience has regrettably shown this to be the case.

The current status of the Review Programme

The first list of review substances to be evaluated contained 90 widely used active substances, representing approximately 30% of the total agricultural market. As of April 2001 the situation for the first list of 90 substances is:

- Annex I inclusion decisions taken on 11 substances.
- Non-inclusion decisions on 16 substances.
- Some 63 substances are in various stages of discussion before Annex I decisions.

¹ ECPA, 6 Avenue E. Van Nieuwenhuyse, 1160 Brussels, Belgium.

Overall, the Review Programme has fully processed 27 active substances. There are still almost 300 active substances to be reviewed by the deadline of July 2003, excluding List 4 (substances of low concern). Industry has voluntarily withdrawn over 300 active substances.

It is generally acknowledged by the Commission, Member States, and industry alike that Directive 91/414/EEC is a very complex piece of legislation with extremely ambitious goals, particularly concerning the Review Programme. Although progress has been made, it has taken years to put the resources in place and to build experience with necessary implementation procedures and guideline documents, a process which has involved the EU Commission, EU Member States, industry and academia, and is still on-going. Likewise, the required confidence and trust between the Member States was slow to develop. The Commission itself recognised this in its White Paper on Food Safety (January 12, 2000) which states "The approval procedure of new pesticides needs to be accelerated" while "In parallel, the review of the approval of existing pesticides needs to be streamlined....".

Progress has clearly been made. The experience with the EU approval process for active substances clearly shows that technical harmonisation, which was a key objective of the Directive, is well advanced, whereas the legislation and the procedures for decision-making need to be improved to expedite the inclusion of active substances in Annex I and to achieve the ambitious aims set out in the Directive. In addition, the Commission continues to introduce measures to improve co-operation between Member States and optimise the use of limited resources.

The way forward for the Review Programme

There is broad agreement within industry that timely implementation has been, still is, and will continue to be a significant challenge, notwithstanding sincere attempts on the part of the Commission, industry, and Member States to improve the situation. This challenge will become even more pronounced in the context of the Second and Third stages of the Review Programme, and in the context of the EU enlargement process, which may see an additional 10 to 13 inexperienced new Member States in the EU.

It is for these reasons that ECPA is recommending a "step change" in the EU approval process via the establishment of a Central Evaluation Unit for CPPs active substances under the umbrella of the proposed European Food Authority. Such an Evaluation Unit would cover the entire evaluation

and recommendation process for active substances, from dossier submission up to and including the Annex I decision recommendation, but not the actual Annex I decision which would remain the Commission's responsibility (with the Standing Committee on Plant Health).

Whilst it is vital that the experience gained to date is built upon, it is also clear that more fully dedicated Community resources are needed to effect successful implementation of the Review Programme. It is vital that any EU regulation and especially regulation in the food sector is credible to ensure public confidence in industry and EU institutions. If the evaluation of CPPs is placed under the new European Food Authority, it is essential that the CPP Evaluation Unit is given adequate, dedicated resources in terms of staff and budget. The unit must have the ability and capability to ensure efficient and balanced regulation and communicate effectively with all stakeholders.

There must be adequate and continuous dialogue throughout the review process, allowing for consultation with the data providers from industry at each step, and ensuring that any considered outcomes are visible to the notifiers.

As previously stated, there is an absolutely vital need for an extension of the Review Programme beyond July 2003. ECPA recommends that the Review Programme be extended with the possibility to consider a further extension should

this be required. ECPA also recommends a "step change" in the approval process by establishing a Central Evaluation Unit operating within the proposed European Food Authority. This unit should be adequately resourced, ensuring the ability and capability to achieve an improvement from the present level to at least 40 dossiers per year.

The crop protection industry remains committed to a science based risk assessment process, as is demonstrated by an industry investment of nearly Euro 1.000 million to complete the Review Programme.

It is vital for the crop protection industry and for European agriculture that the Review Programme is extended for an adequate period of time. Without an adequate extension, some 700 plus existing active substances will have to be withdrawn from the market by July 2003. This will have disastrous consequences, not just for industry, but first and foremost for European agriculture and for society as a whole.

The crop protection industry is dedicated to ensuring that its products are consistent with the aims of sustainable crop protection, and it is important that the EU regulatory framework is compatible with this aim to introduce new innovative products which are economically viable, socially acceptable, and safe for farmers, consumers, and the environment.

SOCIETY OF TOXICOLOGY (SOT) CONFERENCE

The annual SOT conference was held from March 25-29, 2001 at San Francisco, CA.

The most heavily used herbicide in the USA (and in the world), atrazine, had 10 posters and several mentions in platform sessions. The most heavily used insecticide in the USA, chlorpyrifos, also had a large number of posters (21). Both pesticides have been subject to extensive regulatory activity over the past 12 months.

Atrazine

Much of the work had already been published, but the conference have a good opportunity to question the researchers. Some of the subjects covered were:

- Multiple measures of worker exposure (LADD) (Selman *et al.*, Syngenta)
- Estimation of human dermal absorption, metabolism and elimination (Simoneaux *et al.*, Syngenta/UCSF)
- Pharmacokinetics in rhesus monkeys and humans (Maibach *et al.*, UCSF, Syngenta)
- Immunotoxicity of atrazine in mice (Fan, Zheng and Pruett, LSU, LA)
- Mechanism of LH block and endocrine hormone imbalance in the development of mammary tumours in

female SD rats (Cooper *et al.*, US-EPA, RTP)

- Risk factors in the development of atrazine-induced mammary tumours (Breckenridge *et al.*, Syngenta)
- Evaluation of the relative potency of a series of 9 phenylalkanes based on bisphenol A

It remains to be seen whether triazine herbicides cause an induction of aromatase in female SD rats (and, presumably, not in the F-344 strain). This inverse toxicology would provide a plausible mechanism for the atrazine-induced mammary adenocarcinomas in the SD rat. However, it could also indicate a similarity in reproduction systems between this strain of rat and humans, that Syngenta has been keen to dispel, with uncertain regulatory consequences.

Chlorpyrifos and other ChE inhibitors

Studies of the various endpoints of chlorpyrifos toxicity by Dybowski *et al.* (Dow AgriSciences) and a guinea-pig model system for assessing chronic exposure to nerve gas agents (sarin, VX, soman) showed the importance of RBC ChE as an indicator of exposure to a ChE inhibitor, without it necessarily being a valuable marker of toxicity.

Derek Gammon, CalEPA