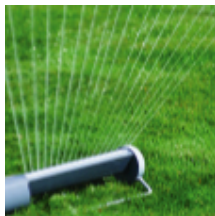




Proposal for a Regulation of the European Parliament and of the Council concerning the placing of plant protection products on the market.



ECPA position following the 1st reading of the European Parliament and the Council political agreement

Brussels

1 September 2008
MISC/06/EJ/15503

Background

The aim of this paper is to provide the opinion of the crop protection industry on the proposal for a Regulation of the European Parliament and of the Council concerning the placing of plant protection products on the market. The document takes into account the views expressed by the European Parliament in their first reading completed in October 2007, as well as the position expressed by the Council of Agricultural Ministers who reached a political agreement in June 2008.

Introduction

The innovative crop protection industry remains committed to maintaining investment in Europe. This is in order to ensure both the re-registration of existing products and the research and development of new products that meet the high safety and environmental standards required by the public and by farmers to effectively control pests.

It is essential that the new legislation provides a framework that encourages such investment – putting in place a predictable system and ensuring the protection of intellectual property.

Basic principles

Directive 91/414/EEC is based on sound scientific principles and provides a comprehensive framework for the continued protection of human and environmental safety. As far as possible, we believe that any changes should be confined to those essential elements, which improve the regulation of plant protection products (PPPs) and cannot be accommodated within the existing text.

The major policy concern – hazard-based cut off criteria

Key messages:

- ***There is no need to ban substances that have passed the strict risk assessments currently in place***
- ***There is no evidence that cut-off criteria will increase safety (it may have a negative impact with increased use of the remaining products required to control pests)***
- ***Cut-off criteria will make sustainable agriculture more difficult***

ECPA does not in principle support the use of hazard based cut-off criteria and supports an evaluation system that continues to be based on a proper scientific risk assessment. We believe that decisions should be based on a technical/scientific evaluation and not on criteria that do not take into account the risks associated with the actual use of plant protection products. Furthermore we believe that only such provisions can be included in the law where the triggers that should be used are clear and accepted by the scientific community, what is not the case concerning “endocrines”.

The use of the proposed cut-off criteria would lead to the removal of many products from the market based on simplistic hazard criteria without any consideration for risk assessment. Such a system could particularly impact substances that are essential for the protection of minor crops and for resistance management, thus playing a key contribution in the sustainable use of plant protection products.

The first reading of the European Parliament introduces additional cut-off criteria that would remove over 60% (and possibly over 80%) of the substances currently authorised and used in the EU¹, while the first reading in the Council of Ministers confirmed in general the proposed hazard based cut-offs of the Commission that would remove possibly up to 25% of the substances currently available. Such a loss of substances would make it unviable to continue the production of many key crops in the European Union. As the consumer demand for these crops remains at a high level they would have to be imported from non-EU countries resulting in a serious disadvantage for EU farmers.

Depriving European agriculture of the necessary tools to produce good quality food at a price affordable for all appears contradictory to growing concerns about the development of prices for basic foodstuffs which form an essential part of a nutritious diet. Farmers should be allowed to use safe plant protection products as a last line of defence to protect their harvest against pests and diseases especially as the pressure to feed an ever growing world population using less and less farmland per person is growing.

To maintain a risk-based system, ECPA remains convinced that the hazard based cut off criteria should be limited to internationally agreed guidelines such as the Stockholm (POPs) Convention.

Assessing the impact of the cut off criteria

While the discussions on this Regulation have been on-going for over two years, ECPA remains concerned that the impact of the cut-off criteria have not been fully assessed at the EU level, and many important questions remain unanswered.

The scientific community has expressed doubts about the provisions being proposed, and we believe that further assessment is required. While the impact on productivity, food pricing and food security has been stressed, ECPA would also highlight that other assessments require consideration to ensure a fully informed decision making process:

- The European Food Safety Authority and specifically the PPR Panel have not been requested to give their opinion on the wider impact of the cut-off criteria on possible improvements in the safety of plant protection products. ECPA believes that such an assessment is essential.
- Given the importance of many of these products for sustainable agriculture, an assessment is necessary to understand the overall impact on the use of the remaining products, and the potential risk of greater resistance development.

5-year derogation for active substances of concern

An important element of the Council common position is a new provision which introduces a derogation for certain active substances where there is evidence that an active substance is necessary to control a serious danger to plant health which cannot be contained by other available means (Article 4.7).

ECPA welcomes the recognition that the identified substances can and are today being used safely by European farmers. While we welcome the fact that some flexibility is introduced, we believe that this measure needs to be further considered, with greater flexibility to allow decision making at national level based on a strict risk assessment, and including clearer definition of how and when such derogations will apply.

¹ According to an evaluation by the Pesticide Safety Authority, up to 85% of active substances could be lost

Other important provisions under discussion

Comparative Assessment & Substitution

ECPA believes that the current risk assessment approach of Directive 91/414/EEC is sound and should be kept. While not supporting the substitution of products that meet the basic decision making criteria set out in current EU legislation, ECPA recognises that there is a political demand for a system of comparative assessment at the regulatory level.

ECPA is concerned at the large number of substances that may be considered as 'candidates for substitution', and believes that a more targeted approach is necessary to ensure a workable system that can be efficiently implemented by the regulatory authorities.

While the Commission proposal limits the authorisation period for active substances labelled 'candidates for substitution' to seven years, we welcome the Council suggestion for a 10 year period of authorisation of the active substance, with a review of the authorised products to be carried out by the Member States every five years. It should however be stressed that measures requiring the regular re-review of 'candidates for substitution' will affect business predictability thereby discouraging innovation and contributing to the ongoing reduction in the tools available to growers.

The European Parliament first reading limits the authorisation of 'candidates for substitution' to one approval of five years – resulting in a *de facto* phase-out of the substance concerned. According to the suggestions of the European Parliament even substances that do not fall under the criteria of "candidates for substitution" should be subject to a comparative assessment. Such a situation would mean a further loss of active substances, leaving no crop protection tools for farmers in many situations.

Consequently ECPA suggest to replace the criteria for approval of active substances as "candidate for substitution" (Annex II point 4) with the cut-off criteria (Annex II points 3.6.2, 3.6.3, 3.6.4, 3.7.2, and 3.7.3)

Parallel trade

While the Commission's proposal provides no legislative provisions concerning the parallel trade of plant protection products, we welcome the Commission and Council's support for the provisions included in the Parliament first reading (Article 49a). ECPA believes that parallel imported products should provide the same guarantees as the nationally authorised crop protection products, especially with regard to protection of human & animal health and of the environment. The agreed Regulation therefore should include, among other steps:

1. a systematic verification that the imported product is from the same source and is identical to a product authorised in the importing country,
2. a verification that the product has not been re-packaged
3. a verification that the product is imported from that Member State where it is approved,
4. a strict application to the imported product of all conditions associated with the authorisation in the importing country.
5. a right to be heard for the authorisation holder of the reference product

National Provisional Authorisations

Given the investment and time needed to bring a new product to market, ECPA supports the changes proposed by both Council and Parliament, to maintain a system of National Provisional Authorisations (Article 29a on Council text). It is essential that the revised legislation continues to provide early access to the market for improved crop protection products that have been fully evaluated in line with EU registration guidelines. While we

welcome the strict 2.5 year review timelines for new active substances, ECPA remain concerned about the ability of authorities to meet these timelines, and also about the ability to establish EU MRLs in the same timeframe. In the absence of NPA's, failure to do either could significantly impact the introduction of new product innovation.

Indeed, given the very high cost of developing a new active substance, it is essential that an early return on investment is possible. Removing the current system of national provisional authorisations would increase the time to first market access to 4-6 years, compared with a period of around two years at present. With an average cost of developing a new active substance of €200 million, such a delay in market entry would have a major impact with average losses of sale valued at €80 million per active substance.

Data Protection

The proposal introduces a new and innovative way to improve the functioning of the EU data protection provisions for plant protection products. ECPA supports the proposal to simplify the legislation and link the protection of all data to a "first authorisation", as set out in Article 56 of the draft text. We support a concept that protects all data that is considered as 'new and necessary' for a 10-year period from the time it is first used for any authorisation, but not limited to GEP- and GLP-data.

For new active substances, we believe that a longer data protection period should be considered and ECPA fully supports the agreement between all the institutions that such additional protection periods should be linked to the authorisation of a number of minor uses.

For the renewal or review of existing registrations, ECPA welcomes that the Council is in line with the Parliament to give an exclusive use data-protection period for new and necessary data. ECPA calls for the re-introduction of the Parliamentary proposal for an additional 10 years data protection, and for clarification concerning data protection for minor use extensions in relation to renewals.

Zonal authorisation and mutual recognition of authorisations

ECPA supports the initiative to increase co-ordination and worksharing within the product evaluation process, and believes that the Council proposal as it stands will provide some of the worksharing benefits that industry and regulators would like to see in future. Although ECPA agrees with Parliament that the division into 3 zones does not take full credit of the diversity within the EU, ECPA believes that working in zones and the introduced possibility to work across zones could provide opportunities to improve worksharing in product evaluations. In this context it is important that final authorisations are granted at the Member State level, allowing Member States to take into account specific national environmental and agronomic conditions. As these conditions do not play a role for applications for use in greenhouses, as post-harvest treatment, for treatment of empty storage rooms and for seed treatment,

ECPA welcomes the suggested single evaluation in these cases. ECPA also welcomes the possibility to mutual recognise: 1. across zones; 2. candidates for substitution, provisional authorisations and derogation clause PPPs as introduced by Council. ECPA is however concerned about the introduced possibility for 3rd parties to apply for mutual recognition if there is a general Member State interest. The consent of the authorisation holder is needed, but refusal can be overruled by the Member State on grounds of public interest.

Transparency

ECPA welcomes the suggestion put forward in the Parliament first reading (Article 60) that study reports can be viewed by interested parties in specific locations, but copies or any

other means of publication should not be accepted, and suggests the re-introduction of this amendment in the second reading. The text agreed by the Council would provide competitors with free access to key know-how information as well as to actual studies that could be used to gain authorisations on third country markets. It also raises privacy concerns for individuals involved in study conduct, whose names will become widely available under the Council proposal.

Conclusion

ECPA's main aim is to ensure a workable and sustainable system of regulation, which is science-based to protect health and the environment, and which ensures that consumers have access to affordable, quality fresh foods. ECPA will remain a committed partner to the EU institutions throughout the legislative process.