ECPA position: Regulatory considerations to encourage industry investment in minor use authorisations.

"The crop protection industry's preference would be for a streamlined Regulatory process that removes unnecessary regulatory barriers and provides the economic incentives for industry to invest –minimising the need for specific rules and exemptions for minor uses."

Brussels
17 May 2010
PP/10/EJ/19737

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Regulatory considerations to encourage industry investment in minor use authorisations

EXECUTIVE SUMMARY

The aim of this paper is to consider the wider regulatory framework for plant protection products and to suggest changes that would provide greater incentives for industry to invest and provide a wide range of crop protection solutions, including for speciality crops and minor uses.

The crop protection industry believe that further consideration needs to be given in the implementation of the regulatory framework to maximise the "economic incentives for industry" to invest in a wide range of uses for all products on the market.

The crop protection industry's preference would be for a streamlined Regulatory process that removes unnecessary regulatory barriers and provides the economic incentives for industry to invest –minimising the need for specific rules and exemptions for minor uses.

To achieve a streamlined process, ECPA believe that the following areas need to be addressed:

- **Data requirements** –Consideration needs to be given to the opportunities for using extrapolated data from one single crop to allow the authorisation of a number of crops.

- **Guidance documents** – The development and implementation of guidance documents needs to be simplified to ensure a more straightforward and consistent process.

- **Zonal authorisation and mutual recognition** – The zonal authorisation system does provide a framework for more cooperation between Member States. But progress needs to be made to remove unnecessary national requirements that substantially increase costs and have a disproportional impact on the authorisation of minor uses.

- **Comparative assessment** – The introduction of a system of comparative assessment substantially increases the uncertainty of the legislative process. Partial substitution of products should be avoided: the removal of major uses would in most cases make a product unviable and would have a particularly detrimental effect on minor uses.

AIM OF THE PAPER

With the entry into force of Regulation 1107/2009 and its full application from June 2011, a number of measures have been put in place in order to encourage the authorisation of minor uses. These positive measures should not however be considered in isolation as the availability of crop protection products for minor uses is greatly influenced by the wider regulatory framework.

The aim of this paper is to consider some of those elements of the wider regulatory framework and to suggest possible improvements that would provide greater incentives for industry to invest and provide a wide range of crop protection solutions for all crops including for speciality crops and minor uses.

INTRODUCTION

A large number of crops grown in Europe that are of major importance for the food industry and consumers are relatively minor, both in scale of production and also in their use of crop protection products. While the magnitude of pest problems faced in these crops is similar to major crops, many efficient plant protection solutions are often unavailable for economic reasons.

The completion of Regulation 1107/2009 on the authorisation of plant protection products recognises that "t*he economic incentive for industry to apply for an authorisation is limited for certain uses, (and) in order to ensure that diversification of agriculture and horticulture is not jeopardised by the lack of availability of plant protection products, specific rules should be established for minor uses"*[1].

These specific measures are the focus of continued discussions between the Commission, authorities, the crop protection industry and other stakeholders in the food chain. The conclusion of the Workshop on "Speciality crops and minor uses", organised in November 2009 provides a common view on further developing the specific measures for crop protection[2]. The crop protection industry fully supports the Conference conclusions, which highlight the need for greater coordination and cooperation, and requests an EU minor use fund to support such initiatives.

This paper will not look at the issues covered in that Conference. It will look at broader issues
, as the crop protection industry believe that further consideration needs to be given in the implementation of the regulatory framework to maximise the "economic incentives for industry" to invest in a wide range of uses for all products on the market.

The crop protection industry's preference would be for a streamlined Regulatory process that removes unnecessary regulatory barriers and provides the economic incentives for industry to invest –minimising the need for specific rules and exemptions for minor uses.

This paper looks at some of the areas where ECPA and the crop protection industry believe that further consideration is needed within the framework of the legislative process to encourage continued investment.

[1] Paragraph 30 of the preamble to regulation 1107/2009
[2] See here for the Conclusions of the Speciality crops and Minor uses Conference, November 2009.

COST OF INNOVATION

In considering investment in the crop protection sector, it needs to be recognised that the estimated cost of introducing new active substances onto the market is about €189 Mio[3]. In addition, there are also substantial costs in upgrading the data to meet the new data requirements – and ensure the maintenance of the active substance approval at the EU level as well as that of the product at national level. These high costs lead to the situation that PPP companies are primarily looking for PPPs being developed for major crops, with the period required for a return on the investment in minor crops would be too long.

A limited budget is available for each product project being developed by companies. Streamlining the requirements would therefore decrease the cost of gaining authorisations for each use, and would allow companies to invest a greater proportion of the available funds in ensuring the authorisation a wider number of uses.

Applications for the authorisation of minor uses and speciality crops are often more resource demanding given the fact that they are very often used in fresh food commodities where the application of the product is at a late stage, leading to a correspondingly short pre-harvest interval (PHI) and a higher level of detectable residues. The need for such additional resources often make the proposed uses commercially unviable and consideration needs to be given to simplified procedures that could therefore assist and streamline the authorisation process for minor uses.

KEY RECOMMENDATIONS – MAINTAINING ECONOMIC INCENTIVES

In order to maintain the necessary economic incentives to invest in a wide range of uses, ECPA believes that a number of areas have to be addressed to ensure a pragmatic approach in the authorization process. The crop protection industry have identified a number of areas and issues where changes would be helpful and/or where consideration should be given to minimize unnecessary requirements.

Key areas identified by industry are:

- **Data requirements** – In parallel to the discussions on the new Regulation, work is on-going to update the data requirements for the submissions of EU dossiers for active substances and products. Consideration is also being given to the updating of the Uniform Principles , which set out the harmonised criteria for the evaluation of plant protection products. In amending the data requirements, options for reducing the cost burden of data need to be considered while at the same time ensuring that the data meets today's rigorous scientific standards. Consideration needs to be given to the opportunities for using extrapolated data from one single crop to allow the authorisation of a number of crops.
- **Guidance documents** – The process of developing guidance documents has become more complex with responsibility having moved to EFSA. While the guidance documents must meet the highest scientific standards, industry believes that this can be achieved in a less complex framework. The practical development and implementation of guidance documents needs to be simplified to ensure a more straightforward and consistent application.
- **Zonal authorisation and mutual recognition** – The introduction of the zonal authorisation system does provide a framework to ensure more cooperation and consistency in the authorisations granted by Member States. A further effort is now needed to ensure national acceptance of evaluations carried out by another Member

[3] Phillips McDougall report, 2010

States in the same zone. Many unnecessary national requirements remain and this is particularly true for efficacy data, where a large proportion of Member States are unwilling to accept efficacy data from a neighbouring country. These situations substantially increase costs and have a disproportional impact on the authorisation of minor uses.

- **Comparative assessment** – The introduction of cut-off criteria and a system of comparative assessment substantially increases the uncertainty of the legislative process and greater clarity for industry would ensure that industry investment could be focussed on those areas which offer the greatest opportunities for the future. In any comparative assessment process, it is vitally important to recognise that the partial substitution of a product (e.g. removing the major uses from the label while maintaining minor uses) would in most cases make a product unviable and would have a particularly detrimental effect on minor uses.

ECPA will be looking in more detail at some of the issues that the crop protection industry believe require further consideration in order to simplify the regulatory procedures and ensure that a high level of economic incentives remain for industry to provide the solutions required by European farmers. These analyses will be made available in due course to highlight the need for a streamlined process to assist minor use authorisations.