

AGRI-FOOD CHAIN ROUND TABLE FOR PLANT PROTECTION

Proposal for a Pan-European authorisation of Plant Protection Products for Speciality Crops

THE PROBLEM

FARMERS GROWING SPECIALITY CROPS FACE AN IMPOSSIBLE CHOICE

The European and Member States' current Plant Protection Product (PPP) authorisation process fails to provide a level playing-field for farmers growing Speciality Crops, continuing to create barriers to production and distortion in the internal market.

Speciality Crops, by their very nature, cover relatively small planted areas in a given country, and therefore require relatively small volumes of a wide range of PPPs for their protection (small volume requirement, translates into 'Minor Use').

Whilst farmers in one country may have access to a complete range of authorised PPPs, their neighbours a kilometre away in another country, may have no authorised PPP options available, and are confronted with these three options:

1. Not to grow the crop they want to produce
2. Grow the crop and risk crop failure
3. Grow the crop, apply PPPs which are not authorised in that particular country, and risk prosecution

None of the above options are acceptable, and farmers should have a choice, other than to abandon their crop. This is the vision of Europe in creating the Minor Uses group.

WHY ARE THERE MAJOR DIFFERENCES BETWEEN MEMBER STATES?

NATIONAL AUTHORISATION

Expensive: For a PPP to be authorised for use in a single European country on a given crop, extensive, time consuming and extremely costly data packages must be submitted to the national administration for their approval. These data packages are generally submitted by the manufactures of plant protection products wishing to sell the products.

Time consuming: There is no shorter procedure for minor uses authorisation and the benefits of the zonal and mutual recognition systems have provided limited benefits. The manufactures of plant protection products and the farmers wishing to buy and use the PPPs, must wait for the national administration to process the data and to make a decision whether or not to authorise the PPP for use on the crop. Significant differences are observed in the time taken for different Member States to process data packages.

Speciality Crops are often not cost-effective for Plant Protection companies: Manufactures of plant protection products (conventional chemical as well as non-chemical) have no commercial incentive to seek authorisation when a given crop's national production area, does not support sufficient sales of a PPP to generate an adequate return on investment.

New crop protection gaps are identified every year, as a result of loss of active substances or products or due to new pest pressures in Speciality Crops. E.g. the lack of insecticides for instance is

very obvious in Southern Europe, as is the limited availability of herbicides for vegetable crops and the lack of new fungicide modes of action for disease control.

Gathering the necessary residue data package is a significant hurdle to registration projects in minor crops, in terms of time and cost. Despite in Point 3.2.2. of Reg. 283/2013, some flexibility in the requirements for tests in minor crops is provided, this has not been widely used in practice. The continued division of EU into 2 residue zones multiplies the costs, which could be reduced by defining a single residue zone for minor crops – or by accepting relevant studies from other zones as the differences between individual sites are often larger than between the zones.

ACCESS TO PPPS FOR SPECIALITY CROPS IS EXPECTED TO GET WORSE

With a number of proposed implementation measure and policy changes linked to Regulation 1107/2009, there is a concern that this may lead to the removal of 1 in 3 active substances on the European market. The impact of the hazard classification of active substances is a particular area of concern.

ZONAL AUTHORISATION

EC Regulation 1107/2009 introduced the concept of three European zones, and made provision for National Authorisations to apply within a zone, providing other Member States chose to accept the authorisation. After several years of operation, it must be concluded that Zonal Authorisation does not work, as Member States, with a few exceptions, do not embrace the Mutual Recognition concept.

The principle of separating Europe into three zones, designed to group countries with similar climatic conditions, adds unnecessary complication, given that for each crop, most weeds, diseases and pests are common across Europe and the chemical solutions are also the same. Differences in Agro-Pedo-Climatological conditions and techniques are often more diverse within the administrative limits of one country than across the borders in neighbouring countries, or even in neighbouring zones.

THE SOLUTIONS

A number of changes are needed to improve the functioning of the regulatory system for Speciality Crops. Whilst some of these changes would require amendments to current legislation. Some major improvements could also be achieved within the current regulatory framework, if a major change of Member State mindset could be brought about, delivering a clear political commitment to the correct application of the zonal and mutual recognition procedures set out in Regulation 1107/2009.

The following areas, which could lead to significant improvements:

Definition of ‘Minor Uses’ and ‘Speciality Crops’

European level co-operation is essential in order to find ‘minor use’ solutions for Speciality Crops. Such cooperation would be facilitated by a common definition of minor uses and/or Speciality Crops. An EU level definition is essential and this should be largely based on the importance of the production (in terms of either European planted area or tonnes of production). While this should be agreed and incorporated into legislation by the Commission and Member States, an informal agreement on common definitions should be agreed between Member States in the short term.

Consequently, the EU Minor Uses Coordination Facility would benefit from such a common definition – as their work could focus on promoting cooperative projects for an agreed list of Specialty Crops. A common definition would also help the co-financing of registration projects via consortia of stakeholders, including national/regional authorities. Further solutions could be provided in the future with the support of an expanded central budget (similar to the IR-4 in place in the USA).

EU wide authorisations for Speciality Crops and minor uses

There is a need for an EU-wide authorisation for Speciality Crops and minor uses. Whilst the current legislation neither requires nor prescribes such an EU level authorisation, there is scope for the Member States to make better use of the zonal and mutual recognition system to ensure that minor use authorisations are granted throughout the EU.

➤ **Interzonal cooperation**

In particular, close cooperation between zones would allow a rapid evaluation of minor use applications, especially where the main evaluation work could be carried out by a single Member State – being rapidly reviewed and accepted by the rapporteur MSs in the other zones.

➤ **Single EU residue zone for minor crops**

The continued division of EU into 2 residue zones increases costs, which could be reduced by defining a single residue zone for minor crops – or by accepting relevant studies from other zones as the differences between individual sites are often larger than between the zones.

➤ **Making use of current mutual recognition provisions**

Whilst the current provisions of Regulation 1107/2009 allow Member States to authorise a product by mutual recognition from a country that is not within the same zone¹; it is essential that greater use of this provision is made, to support additional authorisations for Speciality Crops.

➤ **Legislative changes – one zone concept**

While major improvements are possible in the national application of the zonal process and mutual recognition, further improvements can also be achieved by making changes in the legislation. The application of a 'one zone concept' – and not just for evaluation but also for authorization - would be helpful for minor uses. The provision for a one zone evaluation already exists within Regulation 1107/2009 for plant protection products used in greenhouses (protected crops), in storage or as a seed treatment. Through this provision an evaluation by one Member State enables an authorization throughout the EU, through zonal application or mutual recognition (art. 33.2(b)). The application of such provision to Specialty Crops and other minor uses should provide benefits, if accompanied by the political motivation to apply the legislation correctly.

A next step, which would require legislative change, would be a true one zone concept, i.e. including one zone authorization, where the result of the evaluation of a minor use, would be an European authorization for this use. This would save time and money consuming procedures for zonal application and mutual recognition, and would be justified, as all risks would already be evaluated, and be minor in nature, since it concerns minor uses.

➤ **Forthcoming legislative review**

Given the ongoing evaluation of both Regulation 396/2005 and 1107/2009, there is a need to carry out a detailed review of the application of the current provisions on minor uses and Speciality Crops. A review of the improvement options is particularly necessary, in order to help the Speciality Crop sector manage the major pest challenges that they face.

¹ Regulation (EC) No 1107/2009, article 40.1(a)