



Position Paper On Speciality Crops and Minor Uses

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Executive Summary

The sustainable production of food and high value crops is vital for both human health and national economies. It contributes to agricultural productivity, varied and nutritional food supply, and food security. For the growers of speciality crops and for minor uses, this sustainability can only be realised by the continued availability of crop protection solutions for weed, pest and disease pressure. The goal for all stakeholders is to maintain this availability, given the economic, regulatory and market challenges.

CropLife recognises that speciality crop and minor use issues provide a challenge to all stakeholders involved, and in particular regulatory authorities. In this context, CropLife supports initiatives and specific arrangements to facilitate and improve access to crop protection products for specialty crops and minor uses. The plant science industry can contribute expertise and knowledge to ongoing efforts to increase the availability of crop protection products for specialty crops and minor uses.

- CropLife supports mechanisms that facilitate the registration of minor uses, such as extrapolations and reduced number of trials if those are based on the principles of sound science and within precise guidelines commensurate with the protection of human and environmental safety.
- Other incentives, such as reduced administrative fees and expedited reviews to facilitate applications can also be beneficial: They provide an economic stimulus to the registrants of crop protection products and increase the availability of new crop protection technologies to growers.
- In return for registering product uses for speciality crops or minor uses, registrants should be granted periods of PRD, which are in addition to the 10 years minimum period of PRD advocated by CropLife. Consideration should also be given to the continued availability of crop protection solutions for specialty crops and minor uses during post-registration re-evaluation programmes.
- CropLife International recognizes the importance of support from the registrant for minor uses advanced in third-party regulatory submissions. Regulatory authorities have the key role to assure that registrants are in agreement with all minor uses that are granted.

Introduction

The sustainable production of food and high value crops is vital for both human health and national economies. It contributes to agricultural productivity, varied and nutritional food supply, and food security. For the growers of speciality crops and for minor uses, this sustainability can only be realised by the continued availability of crop protection solutions for weed, pest and disease pressure. The goal for all stakeholders is to maintain this availability, given the economic, regulatory and market challenges.

The economic, regulatory and market challenges can be substantial for individual CropLife members and in certain individual circumstances can lead to a loss of commercial interest in minor uses by individual companies. Whilst commercial success can be derived from registering uses on speciality crops and minor uses, the actual economics differ on a case-by-case basis and assessing and deciding on commercial interest is entirely the prerogative of the individual companies.

Recognising the challenges to industry arising from potentially limited commercial opportunities, combined with substantial regulatory hurdles, some governments provide incentives to companies in return for registering uses on speciality crops and for minor uses. However, governments may also provide liability waivers to third-party registrants, which can potentially have severe negative consequences for primary registrant companies, as the legal validity and status of such waivers are generally untested in the Courts of Law.

CropLife recognises that speciality crop and minor use issues also provide a challenge to governments and their regulatory authorities. Cooperation of industry with governments and organisations concerned with finding crop protection solutions to the speciality crop and minor use problems supports CropLife's advocacy and responsibilities concerning healthy diet; keeps the industry engaged in the political debate on regulatory matters; provides an opportunity to engage with regulatory authorities on wider regulatory aims such as the promotion of "smart regulation"; and creates a platform for improving relationships with other non-governmental stakeholders engaged in matters of registration and regulatory policies.

CropLife therefore supports the availability of crop protection solutions for growers of speciality crops and for minor uses and welcomes supported and funded initiatives that address the significant issues surrounding the area.

1. Topic: Definition of Speciality Crops and Minor Uses

Definitions of speciality crop and minor use are critical precursors to the development of incentives to encourage the availability of crop protection solutions for the control of weeds, pests and diseases. The definitions will vary considerably among countries and regions, based on local agricultural practices and climate. The Organisation of Economic Cooperation and Development (OECD) has prepared a guidance document¹ with the aim of enhancing the consistency among member countries in defining minor uses. That guidance document concluded that any definition should reflect production variables, dietary significance and economic return.

CropLife agrees that the definitions of speciality crops and minor uses should be consistent with the OECD guidance that is they should address significance of the crop (i.e. cultivation area), production variables, dietary intake, and economic return on investment for the manufacturer.

In general, the term "minor crops" includes both food and ornamental crops where the production is less than a certain acreage or tonnage. Minor crops are typically high-value crops such as fruits, vegetables, tree nuts, nursery plants and ornamental crops. Although the term "speciality crops" is sometimes used as a synonym for minor crops, it often refers to a narrower group of minor crops.

The term minor use includes crop protection uses in minor crops as well as uses in major crops where a particular weed, pest or disease problem occurs only in specific limited situations.

2. Topic: Systems, Processes and Tools

CropLife supports the use of systems, processes and tools which provide transparency and availability of information for all stakeholders, i.e.

- the use of processes and tools to identify and prioritise weed, pest and disease control solutions for speciality crops and minor uses through engagement with growers; and
- the development and maintenance of appropriate databases containing current authorisations, data and priorities for weed, pest and disease control solutions.

3. Topic: Support for Multi-party/Government-Private Minor-Use Initiatives

CropLife supports such initiatives only where a framework is in place, where the objectives and goals are clearly stated, and where CropLife, if directly involved, is accepted as equal partner. "Framework" encompasses secured funding and the involvement and commitment of stakeholders from government, regulatory authorities, growers, technical experts, and the crop protection industry. Support needs to be carefully coordinated with ongoing national and regional programs to ensure that consistent messages are provided and optimum use is made of resources.

CropLife, through its extensive industry networks, can offer guidance to developing regions and countries in making contact with appropriate funding agencies.

4. Topic: Economics and Incentives

Intellectual property and data protection

The crop protection industry makes a significant investment in registration data to demonstrate the safety and efficacy of its products. These data are proprietary, and it is CropLife's position that they must be afforded a minimum period of 10 years, during which the data producer enjoys exclusive use of the data for support of crop protection registrations. This protection of regulatory data must extend to data produced for support of new active substances, new formulated products, new crop uses (including major and minor crops), as well as new data produced in response to regulatory data call-ins and for periodic re-evaluations.

Crop Life supports granting additional periods of protection of regulatory data for registrants in return for their registering product uses for speciality crops or minor uses. A secondary registrant is, of course, entitled to perform its own safety and efficacy studies in support of registration of its product, or obtain authorised access to the original data from the data owner. In the latter case secondary registrant's product must be equivalent to that of the data owner.

Preserving existing registrations

Post-registration re-evaluation programmes may reduce the availability of crop protection solutions for growers of speciality crops and minor uses, because of either unsupportable economics or regulatory restrictions. During the re-evaluation process, consideration should be given to the continued availability of crop protection solutions for specialty crops and minor uses.

CropLife supports the continued access for growers to crop protection solutions commensurate with regulatory decisions and economic reality.

Liability

CropLife does not support authorities granting “off label” uses or “supplementary use labels” for a crop protection product without the support of the registrant. However, in countries or regions where this is practiced, liability should clearly reside with the buyer and user of the product. Such liability must encompass product efficacy and phytotoxicity to crops, as well as risks to workers, bystanders and the environment.

Reduced fees and expedited reviews for minor use applications

Incentives, such as reduced administrative fees and expedited reviews to facilitate applications for speciality crops and minor uses, are beneficial to all stakeholders. They provide an economic stimulus to the registrants of crop protection products and increase the availability of new crop protection technologies to growers.

The registration of crop protection uses for speciality crops or minor uses should be based on reviews performed to the same scientific rigor as for other crops and uses (albeit sometimes with a reduced data set) to ensure human and environmental safety.

Since regional and national regulatory and risk assessment practices will differ, the responsibility for safety must reside with the individual registrants, based on appropriate code of conduct and principles, to ensure that there is no unreasonable risk to the consumer or user from a particular use.

5. Topic: Data Requirements

Extrapolations

The concept of crop grouping and representative uses allows extrapolation from field residue trials conducted for one crop to support registration of other crop uses, and should be based on principles of sound science and public safety. Promoting use of crop groups on a global basis will facilitate international regulatory harmonisation and agricultural trade. CropLife supports the multiple initiatives of the International Crop Grouping Consulting Committee.

Reduced number of trials for minor uses

Any reduction in the number of field residue trials required to support applications for speciality crops and minor uses should be commensurate with ensuring the safety of the consumer and, with this proviso, is also supported by CropLife as an incentive to develop minor use crop protection solutions.

Good Laboratory Practice (GLP)

Wherever possible, studies supporting minor uses should be conducted in compliance with internationally recognized GLP standards. Some aspects of field residue trials may be waived from strict GLP compliance on a temporary basis, pending establishment of local research infrastructure and capabilities in the areas where the work is conducted. In any case, the studies should adhere to sound scientific principles and practices.

6. Topic: Uses and Submissions

Integrated Pest Management (IPM)

CropLife supports the appropriate use and coordination of all available technologies to manage weed, pest and disease problems both effectively and safely. The plant science

industry has endorsed IPM practices for many years, and has publicly declared its commitment to promoting IPM. CropLife fully supports the definition of IPM given in the International Code of Conduct on the Distribution and Use of Pesticides²

“Off label” uses

“Off-label” use refers to the use of a product in a manner and/or on a plant additional to those approved and shown on the manufacturer's product label. The use of “off label” approvals is common in the UK and Australia.

CropLife is not supportive of authorities granting “off label” or “supplementary use labels” without the support of the registrants. CropLife would recommend that any “off label” uses are notified to the registrants, allowing a period of comment. This would provide an opportunity for the registrant to highlight potential safety issues associated with the use.

Third party submissions

Third-party applications to regulatory authorities are widely utilized to register crop protection solutions for specialty crops and minor uses. CropLife maintains that the principle registrants must be consulted and provided with the opportunity to highlight important issues of safety, efficacy, and selectivity. Third parties should approach registrants before embarking on a minor use registration program, in order to facilitate the process, make the best use of all available data, and protect the interests of all stakeholders.

7. Topic: Post-Registration Re-evaluation Processes and Label Extensions.

During post-registration re-evaluation processes, crop protection solutions for growers of specialty crops and minor uses are particularly vulnerable to being lost, and many are already being reduced. Where uses are likely to be dropped during re-evaluation, early communication among the registrants, the regulatory authorities, and the user community is highly recommended.

When minor uses added to a product label contribute only marginally to consumer exposure to dietary residues, the level of regulatory review should be commensurate with the level of change in exposure. This practice would facilitate occasional or periodic additions to the label of minor uses needed by growers.

8. Topic: Global Initiatives:

CropLife supports the major global initiatives to facilitate establishment of MRLs for speciality crops and minor crops, such as those conducted by OECD, European and Mediterranean Plant Protection Organization (EPPO) and CODEX.

References:

1. OECD Guidance Document on Defining Minor Uses of Pesticides Series on Pesticides No. 49. ENV/JM/MONO(2009)39, 23rd October 2009
2. International Code of Conduct on the Distribution and Use of Pesticides, Food and Agriculture Organisation of the United Nations, Rome 2002.