

The Crop Protection Industry's Role In Maximum Residue Limit (MRL) Establishment.

Intervention M. Kaethner¹, Bayer CropScience, on behalf of CropLife International

Establishment of National MRLs

National MRLs in many countries are established as part of the regulatory approval process for active substances and product use authorization. Scientific evidence study reports as well as detailed summaries are part of the dossier for regulatory approvals. Dossiers might have up to about 80000 pages where about 50% are related to MRL setting. The development of data for an application can take 400 years of work.

Our sector fully supports the SPS agreement that MRLs should be set following a risk assessment for the intended uses.

Import Tolerances

In cases where uses in the importing countries do not exist or MRLs are lower than in the exporting country, import tolerances at the level of the exporting country have to be established to facilitate trade. Data requirements depend upon whether the substance is already authorized in the importing country. Study reports and Summaries have to be submitted.

In the absence of legal frameworks for setting ITs it is important that countries publish deferral paths to Codex standards and other national MRLs.

Codex Alimentarius Standards for Crop Protection Uses

Submissions to Codex are voluntary contributions by individual manufacturers. Most CXLs are based on the support provided by Crop Protection Industry members. The Crop Protection Industry supports the prioritization process by providing commitments for active substances and MRL support. For substance and MRL support manufacturers submit original reports, a summary dossier and the evidence that the supported uses are authorized. During the evaluation phase technical experts will respond to the scientific question asked by JMPR experts.

CropLife International members participate in CCPR meetings to provide additional information for decision making if needed. A manual on good practices for CropLife International members and interested parties how to work with Codex procedures and the JMPR is available. See

<https://croplife.org/resources/>

CropLife members are supporting national projects and initiatives, for example projects initiated by IR4 or ColeACP on specialty crops and minor uses

Harmonization of Data requirements, Guidance and Tools

CropLife International supports the international harmonization of data requirements and policies for MRL setting. We appreciate very much the initiative and efforts of the APEC forum to provide guidance for Import Tolerance establishment. We think that this guidance allows an effective use of resources in the importing country and provides a transparent straight forward approach for MRL establishment.

CropLife experts contributed with experimental data and e.g. statistical advice to improve tools for MRL calculations and e.g. to combine existing sets of residue studies to set additional MRLs and to increase the reliability of MRL calculations. Significant progress was made through OECD Guidelines and Guidance during the last decade.

¹ Email contact: michael.kaethner@bayer.com

Challenges for the Private Sector

Acceptance of Codex MRLs

Acceptance means that traded commodities containing residue levels in compliance with Codex MRLs are accepted by the importing country. We like to encourage all countries that their national policies e.g. on deferral paths, or import tolerance provisions are published on their public websites. Any Policy or change of national standards should be communicated with sufficient notice with information on transitional measures. Transparency and predictability is of utmost importance for the whole Food Industry in exporting as well as importing countries.

Lack of Harmonization of Data Requirements and Policies

National data requirements can differ largely. Examples are Crop and commodity groups differences, or the Residue Definition.harmonized in Codex. This leads to a situation that Codex crop group MRLs are not transposed into national law and import tolerances for certain commodities are missing. Differences in the residue definition: Residue definitions differ widely between national governments and Codex. This issue leads to different Maximum Residue Limits and contributes to potential trade irritations. MRLs need be set following a science based risk assessment.

Capacity Issues in the Evaluation by the JMPR

Limited capacity in the JMPR leads to postponements for new substances, new uses and the periodic reviews of existing uses. Countries are encouraged to increase their contributions in terms of experts and financial support. Additional contributions of relatively modest amounts would be an excellent investment to support Codex member countries' economies.

Codex Procedures

Codex meeting schedules and JMPR schedules have been established when trade was less globalized than today. Limited capacity and annual meetings in JMPR, CCPR and the CAC provide a rather rigid framework, leading to a minimum gap of 18 months between a national authorization and a CXL. Therefore a modernization of existing procedures and a workflow that e.g. includes acceptance by written procedures in the absence of any concerns could be considered.

Closing Time Gaps in National MRL Establishment

Difference in timing of national MRL setting (from 5 months up to 5 years): There is need for more trust and more joint evaluations by regulators for MRL setting. Import Tolerance applications should be evaluated on the basis of intended uses in exporting countries. Final decisions in the importing countries can then be taken when the final label is available. While additional costs for occasional double work cannot be fully excluded free trade would benefit substantially. National or Regional officials responsible for free trade matters need to work together with their colleagues responsible for consumer protection to address Consumer Protection and Free trade needs when MRLs are established.