July 20, 2016

European Commission Proposal for Criteria for Endocrine Disruptors

Industry View

Background

The European Commission (EC) proposed new criteria to identify endocrine disruptors (EDs) – both natural and man-made – that cause adverse effects to human health or wildlife based on the WHO/IPCS (2002) definition, with possible derogations for crop protection products. Any substance deemed an ED by the new criteria will be banned in the EU, taking a hazard-based approach, "unless strict derogations apply." Before becoming effective, the proposal needs to be voted upon by the EU Member States. The final criteria could be adopted in early-mid 2017 with entry into force relatively soon afterwards.

Industry Position

The plant science industry, represented by the European Crop Protection Association, is voicing serious concern about the proposal. This concern relates mainly to using the WHO/IPCS definition alone for criteria to "identify" EDs which are then subject to specific regulatory action, i.e., a ban based on hazard characteristics unless certain negligible risk derogations are met. Industry is of the view that further elements of hazard characterization, such as potency, should be incorporated into the criteria as these are essential to separate substances of high concern from those of no/little concern.

CropLife Canada is concerned about the impact this EU regulation will have on Canada. The proposed regulation has not introduced proportionate and risk-based criteria for ED properties to maintain existing high levels of protection for human health and the environment. The EC proposal could also result in significant uncertainty and disruption in global agricultural trade with an impact on its entire value chain.

Regulation by Derogation

Derogations have been proposed in the new criteria which would allow an exemption from the hazard-based cut-off. The scope of possible derogations has been widened in the EC proposal from negligible exposure to negligible risk, which means a risk assessment would be required. However, CropLife International is concerned that regulation based on derogation is not a good approach and there still remains a large degree of uncertainty as to how the derogations would be applied in practice. Derogations are by default uncertain and vulnerable to political interference. The current debate on glyphosate is a good example as the decision is purely based on politics. Regulating substances based on risk assessment provides a more predictable framework and better supports innovation than regulating hazards by derogation.

Import Tolerance and Maximum Residue Levels

Import tolerance (IT) and Maximum Residue Level (MRL) setting could be impacted by the new EC regulation. In its proposal, active substances will be assessed against the EC's criteria for ED properties at their time of renewal or for new active substances. If a compound does not trigger the criteria, MRLs can be set under the known process of Directive 396/2005. If the criterion of an active ingredient has ED properties, the derogation would allow for further risk assessment, not an immediate ban. If negligible risk can be demonstrated, the product can still be authorized. In this case, MRL setting is expected to be possible alongside the established process of Directive 396/2005.

For a substance triggering the criteria for ED properties where negligible risk cannot be demonstrated, the compound will not be authorized. In this case, the EC proposal is not clear on how MRLs/ITs would be set, but based on feedback, it is highly likely that no MRLs/ITs could be set. This means that substances will be banned without preceding risk assessment and ITs for food imported from Asia will be potentially set to the default level.

In principle, the introduced derogation allows for elements of risk assessment and limits the number of compounds likely to be impacted by the application of an ED cut-off. However, there is still significant uncertainty on whether agreement will be reached to include the derogations in the final criteria and if so, how these would operate in practice. Therefore, the proposal will still put a significant number of products at risk and potentially limit the tool box of farmers.

Summary

- CropLife Canada is concerned that the EU regulation will have a negative and unjustified impact on agricultural trade.

- CropLife Canada is concerned that the EU has elected to regulate EDs based purely on intrinsic hazard. It is also disappointed that the EC has decided not to include hazard characterization elements (e.g., potency) in its proposal for ED criteria. These aspects are essential to prioritize substances and distinguish those with real potential for harm from those that pose little or no risk.

- The crop protection industry does not support the EC's proposal to include certain derogations from the hazard-based criteria. While these derogations based on certain risk considerations may be useful, we are highly concerned with the principle of regulation by derogation. Regulating substances based on risk assessment provides a more predictable framework and better supports innovation than regulating hazards by derogation.

- The EC proposal on derogations is not clear on how MRLs/ITs will be set on substances that may trigger the ED criteria. If no MRL/IT is set, this will impact both European farmers and global agricultural trade by the loss of respective ITs for certain products.

- Other regulatory agencies in the world have taken a risk-based approach to EDs such as the United States Environmental Protection Agency and its counterpart in Japan. This allows authorities to clearly separate substances of concern from those of no concern and ensures a high level of protection for human health and the environment.