

Agricultural biotechnology is helping meet the world's growing need for food, feed, and fiber while reducing farming's environmental footprint. However, farmers in many countries are unable to access genetically modified (GM) crops due to long regulatory approval timelines and commercialization delays. CropLife International supports sustainable bio-innovation by promoting regulatory policies that are predictable, science-based, and risk proportionate so that agricultural innovations are available to those who would benefit the most.

Government policies and data requirements for the safety assessment of GM crops vary across regulatory authorities globally. The CropLife International regulatory harmonization project has identified studies and approaches that constitute a science-based data package that is sufficient for regulatory decision-making. Leveraging the history of safe use and the familiarity of the technology, data from a core set of studies should be considered first, and additional hypothesis-driven supplementary studies should only be performed if necessary to inform the safety assessment. This focused approach for the evaluation of GM plants is risk-proportionate and can be used as a basis for harmonization of data requirements, providing a more transparent, predictable and consistent framework for global regulation.

During the workshop, we will explore the recommendations of the CropLife International Regulatory Harmonization Project through a hands-on activity. Participants will break into groups to analyze an environmental risk assessment case study and a food and feed risk assessment case study for a GM Crop. These case studies will introduce a problem formulation-based approach to risk assessment and will include a thorough exploration of technical regulatory topics such as when composition data and dietary exposure assessments should be required. The workshop will foster discussion on the principles of risk analysis, as well as fit for purpose governance frameworks, and science-based data requirements.