FOOD AND FEED SAFETY ASSESSMENT FACT SHEET

CropLife INTERNATIONAL

Despite 25 years of safe use, the data requirements for regulatory approval of genetically modified (GM) crops are inconsistent from country to country resulting in added costs, less predictability and longer approval timelines.

In thousands of evaluations throughout those 25 years, GM crops have been repeatedly proven to be as safe as their conventional counterparts. Nonetheless, certain countries require data that does not add value to a safety assessment for humans and animals.

This results in significant delays to commercialization of GM crops, thereby hindering innovation.

It is time to evaluate how food/feed safety assessments are conducted for GM crops, and focus data requirements to address plausible risk.

Safety assessments should focus on a systematic approach to risk characterization.

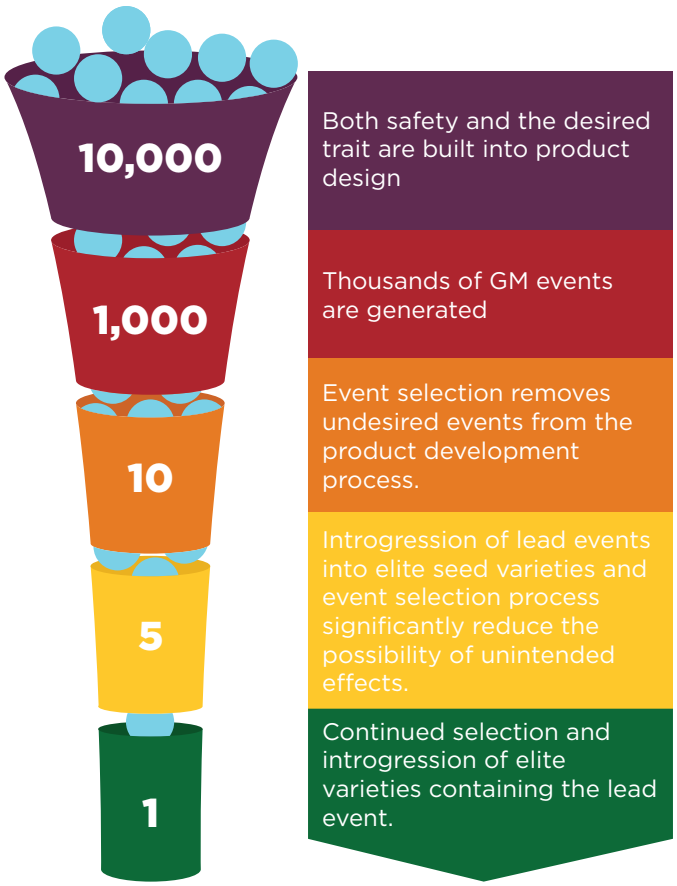
A problem formulation approach should be used to address any questions about product safety. This involves identification of hazard and/or exposure, which are components of risk. A stepwise, weight of evidence method should be followed when assessing the safety of newly expressed substances (protein or DNA) in alignment with Codex Alimentarius principles.

Something hazardous has the potential to cause harm — but only when there is exposure. In the case of GM crops, if there is no identified hazard scenario, there is no risk. As such, a set of core studies are recommended to evaluate safety.

In the absence of hazard, these core studies are sufficient to conclude that GM plants are as safe as their conventional counterpart. However, depending on the type of GM crop and potential for hazard scenarios, there may be a need for supplementary studies to fully characterize risk and assess safety.

Supplementary studies, if needed, should be designed using specific hypotheses around the crop, nature of the introduced trait and/or the intended use. This would help to streamline the review process across jurisdictions and provide a clear, consistent path to commercialization for developers.

The commercial development process for new GM varieties considers safety throughout.



Core studies:

- Molecular and protein characterization
- Safety assessment studies to evaluate hazard (encompassing toxicity and allergenicity)

Supplementary studies examples:

- Compositional analysis should be focused narrowly on components that may be affected by the trait (historically considered to be a Core Study)
- Dietary exposure assessment (DEA), as a lack of exposure would indicate no risk