

Streamlining ERAs for genetically modified (GM) crops can maintain high standards for environmental safety and minimize the regulatory burden for developers.

The goal of all regulatory agencies globally is the same – to protect human/animal health and the environment.

Environmental risk assessments (ERAs) help regulators understand whether GM crops pose any risk to the environment, and if so, how these risks can be effectively managed. ERAs should be conducted using a science-based approach, which uses problem formulation to develop plausible scientific hypotheses on how the GM crop may result in environmental harm.

Risk assessors have more than 25 years of collective experience in assessing the safety of GM crops for cultivation. Despite this experience, problem formulation is not always used, and the collective underlying knowledge about GM crops is not leveraged as part of the risk assessment. As a result, the data that is required for cultivation approvals is not always warranted and assessment methods are not science-based.

Refining and harmonizing global ERA data requirements will add transparency and predictability for product commercialization.

Streamlined and predictable approaches to ERAs can encourage the development of new GM crops that enable new environmentally sustainable solutions to agricultural challenges. A few studies should be universally required to inform the ERAs for all crop and trait combinations. Additional data may be relevant in certain circumstances depending on the crop and trait.

- ERAs should ensure protection goals are met.
- The data that informs the risk assessment for any GM crop is limited. Any additional data should be required on a case-by-case basis if it informs the risk assessment for the specific crop and trait.
- Existing knowledge of GM crops and traits coupled with a history of safe use should be considered when structuring an ERA.
- Data transportability – where studies and/or safety conclusions from one country are leveraged to inform the safety assessment in another country – this contributes to the harmonization and streamlining of regulatory and data requirements.

Almost **370 events** have been approved for cultivation all around the world.

(ISAAA, 2018)

Relevant data for informing ERAs

Relevant for all crops and traits:

- Understanding the growing environment and basic biology of the crop.
- Comparing the agronomic similarities of the GM crop to its conventional counterpart.
- Understanding the intended trait of the GM plant and assessing whether it could lead to environmental harm.

Relevant on a case by case basis:

For crops:

- Assessing potential changes to agricultural practices.
- Generating additional agronomic data on features of the GM trait that may influence the ERA.

For the introduced pesticidal trait:

- Identifying potential harm to beneficial non-target organisms.
- Determining the environmental fate in soil, sediment, or surface water.

Examples of data that does not inform the ERA:

- Molecular characterization
- Composition
- Product efficacy



RISK = HAZARD X EXPOSURE

Risk only occurs when there is exposure to something hazardous