For the last 25 years, genetically modified (GM) crops have been safely grown and consumed worldwide. Farmers planting genetically modified organisms (GMOs) have enjoyed livelihood improvements, as well as environmental and biodiversity benefits, while also mitigating climate change by adopting no-till methods.

Despite scientific consensus around the safety of biotech crops, and the myriad of benefits, many promising new biotech crops still don't reach those who need them. This is partially because global regulations for GMOs are not aligned. Some countries demand extra studies that often don't add value for the assessment of their safety, while others ask for studies to be repeated year after year; even when neighboring countries with the same growing conditions have already completed them.

If different governments had more consistent or similar regulatory frameworks and requirements, agricultural innovations could move more quickly to farmers, which could result in more safe and nutritious foods and the adoption of more sustainable farming practices that benefit biodiversity and the environment.

What is regulatory harmonization?

Today, there is little alignment between governments and their regulatory requirements for GM crops. Instead, individual governments often have their own safety data and testing requirements for GMOs before they will be approved for cultivation or import. This means, farmers may not have access to all the important tools needed to farm sustainably — and farmers in some regions may have an advantage over farmers in other regions in being able to adapt to and mitigate climate change and protect biodiversity, as well as socio-economic benefits.

However, if regulatory requirements across countries or regions became more similar or aligned, then important innovations could move to the market in a more predictable and efficient way — as well as be more equally accessible. This approach is known as regulatory harmonization.

Regulatory harmonization includes a spectrum of different types of alignment between national regulatory frameworks and requirements. Alignment could be anything from governments having consistent requirements for the regulatory review process, to internationally recognized technical guidance documents, standards and principles, to sharing data and assessments, to approving a product if it has already received approval from another regulatory agency.

Aligning on data requirements that industry must submit

Despite Codex Guidelines and resources from the Organisation for Economic Cooperation and Development (OECD) providing the scientific/technical foundation for a common approach to GM food and feed safety assessment, regulatory data requirements vary widely between countries. Familiarity and History of Safe Use (HOSU) achieved over the last 25 years should also enable streamlined approaches.
The CropLife International harmonization project provides recommendations for studies and data requirements that could modernize and align regulatory regimes for GM crops internationally. This is not a new concept. The International Medical Device Regulators Forum (IMDRF) launched a pilot program to enable a single audit for medical device safety and efficacy that has been accepted by participating countries, including Canada and the USA.

Consistent criteria from governments

More data at higher cost does not result in a higher level of safety. The alignment on requirements for the evaluation of GM crops between governments, even on a small scale, would provide valuable consistency for developers facilitating simultaneous submissions in multiple geographies and reducing asynchronous approvals.

Data Transportability

Laboratory and field data generated on GM plants in one country can inform support regulatory decision-making for GM plants in another country. Using this concept of data transportability data across regions has been successfully used by multiple countries to eliminate redundancy, create regulatory efficiencies, and enable timely regulatory approvals.

Safety assessment sharing

Safety assessment sharing refers to the concept of two or more countries sharing their risk assessment conclusions and utilizing those assessment conclusions to inform their own sovereign decision making. Although the scope depends on the agreement, this can be used to share regulatory resources, improve efficiency and synchronization of GM food safety assessments. A good example of how this works in practice is illustrated through the work agreement between Health Canada and Food Standards Australia New Zealand (FSANZ).

Regulatory Cooperation through trade agreements

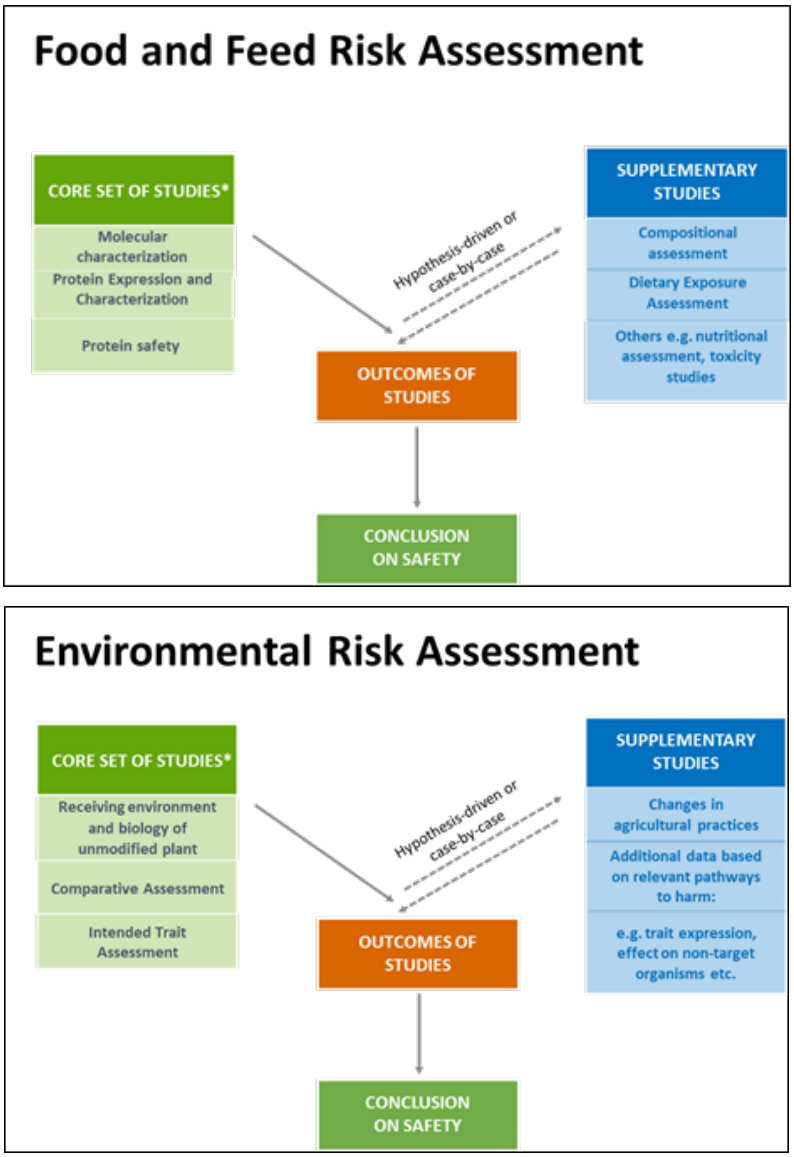
There are also regulatory cooperation agreements that have been facilitated through trading partners. For example, there is a proposal in place for any GM event that is approved by a member state of the Common Market of Eastern and Southern Africa (COMESA) - that will be traded within COMESA - the original country of approval will share its decision documents with receiving countries to facilitate decision-making. For a GM event that has yet to be approved, an application is made through the COMESA Secretariat for an independent risk assessment and subsequent scientific opinion, which is binding on all states. Although this has yet to be implemented, it is a good example of the potential for regulatory cooperation within trading groups.

Mutual recognition

Mutual recognition refers to a single decision authority that will be binding in all member states. A good example of mutual recognition is the European Union where an European Food Safety Authority approval is valid in all member states.

Why do we need harmonized regulations?

Regulatory harmonization not only helps to make innovations available to farmers in a more timely and predictable manner, but it can increase efficiencies in regulatory agencies worldwide and reduce duplication of effort. Regulatory harmonization does not mean that national autonomy needs to be compromised, there are many ways that countries can cooperate without compromising national autonomy from synchronizing on data requirements to sharing safety assessment conclusions.



Core Set of Studies: Studies necessary for a science-based risk assessment of a GM plant.

Supplementary Studies: Studies to be conducted upon identification of information and/or hypothesis that indicates increased risk to the environment or human or animal health. The conduct of these studies depend on the nature of the introduced trait, intended use and data obtained from core studies.

*These are suggested core studies for typical GM plants. There may also be alternative newly expressed substances (e.g. RNAi).