Assessing the Safety of Genetically Modified and Gene Edited Crops

What are GM and GE crops?

The use of genetic modification (GM) of crops such as corn and soya, through the controlled transfer of genes from other organisms into the crop genome, has been used for over three decades to generate GM crops with valuable traits such as herbicide tolerance and insect resistance. More recently, gene editing (GE) has emerged as an alternative biotechnology. With GE, crop genes can be precisely modified to produce well-designed phenotypic changes (e.g., higher yield, different colour or taste, fruit quality or nutritional improvement) without the need to transfer genes from another species.

Genetically modified (GM) and gene edited (GE) crops are both created using modern biotechnology to bring genetic material (DNA sequence) changes to its host crops for the desired crop characteristics or "traits". GM uses various physical or biological methods to insert a fragment of DNA which contains a gene of interest with known function into the plant genome while GE technology precisely targets a specific DNA sequence in the plant genome to bring in the desired changes using tools like molecular "scissors" (e.g., CRISPER-Cas 9). The genetic changes in both GM and GE crops are stably integrated into the plant genome so that they are retained during inheritance of the plant.

Are GM and GE crops safe?

Human beings have a long history of modifying plant genetic materials to create desired species or traits. Technologies such as radiation or chemical mutation, cross-pollination, grafting or polyploidy breeding bring random gene-level changes or large-scale chromosome changes. These changes are random and unpredictable and rely heavily on laborious and time-consuming processes to select the desired outcome. However, they are regarded as "conventional", and the resulting crop or plant products are assumed to be safe. When biotechnology was used to create genetic changes, questions or concerns were raised about the safety of these products.

Many food crops, including maize and soybean have a long history of consumption by humans and animals and are considered "safe"; however, they do contain certain health hazards such as toxicants, allergens, and anti-nutrients (OECD, 2025 and 2024). Therefore, there is no "absolute" safety even of conventionally bred crops but decades of use in the human food chain have shown that the risk to humans from these hazards is usually very low.

The safety assessment of GM and GE crops focuses on whether they are as safe as their non-GM/GE counterparts, by assessing if there are any new hazards which could alter these existing risks not only to humans but also to the environment.

How is the safety of GM crops assessed?

With the assumption that crops from conventional breeding are safe, comparative analysis between a host crop and a genetically modified or gene edited crop is conducted to assess if there will be any increased risk. Hazard and exposure are the two elements to be assessed in order to draw an overall conclusion on safety (hazard x exposure = risk). In essence, if there is no new or altered hazard brought into GM crops, it is likely that they are as safe as their host crops. Similarly, if the exposure to the hazard is low or negligible, it is unlikely to result in an overall risk.

Hazard assessment

Depending on the use of GM crops, different hazards are put into consideration. When used as food and feed, concerns about possible hazards centre around any toxicity, allergenicity and nutritional impacts that can adversely affect the health of humans and animals. A weight of evidence approach is used starting with a literature review of any known safe history of use of the donor organism, gene and the expressed protein. This is followed by an evaluation of the mode of action of the new gene and protein and *in silico* analysis of the protein sequence for similarity to any known toxins, allergens or anti-nutrients. Laboratory studies are then conducted on the expressed protein's physico-chemical properties such as its stability to pH, heat and digestive enzymes. *In vivo* animal toxicity studies are also performed using purified proteins. In addition, to evaluate if GM crops have substantially equivalent compositional and nutritional profile, compositional analysis is conducted to compare GM and its non-GM counterpart simultaneously grown and harvested in typical cultivation regions. Other commercially available and non-GM varieties are usually included as references to reflect possible natural variations of the levels of these components. Animal (normally rodent) feeding studies using diet containing the GM grain are also often requested to further confirm there is no toxicological or adverse nutritional impact, although the value of animal feeding studies using such a diet in safety assessment is debatable.

For environmental hazards, the concern about GM crops focusses on whether or not the introduced or edited genes will increase the weediness or invasiveness potential of these crops, and also whether the altered genes could be accidentally transferred to other sexually compatible plants in

the environment. The assessment first starts with the host crops. For example, in the case of maize and soybean, they are both not considered as weeds or able to persist and spread beyond their cultivation. Where this is not the case, field trials are conducted at multiple locations representative of cultivation regions to provide agronomic and phenotypic comparisons between the GM crop and its non-GM comparators. Laboratory or field comparative studies are also conducted to compare if GM crops would have increased tolerance to physical stressors such as cold temperatures.

Photo of one example field trial location. GM, non-GM and Reference varieties were planted in a randomized complete block design with four replicates and spatially isolated with a buffer zone.

For GM crops containing pesticidal traits, the newly introduced gene(s) and their expressed protein(s) are further characterised for their hazard potential to non-target species. This is typically assessed by ecotoxicological studies using surrogate species in a laboratory setting, and field survey studies to evaluate any unintended effects on living species populations in fields where both GM and its non-GM comparator crops are grown.

Exposure assessment

Even without any hazard identified, exposure is also routinely assessed. For example, the newly expressed protein will be quantified in edible parts of the GM crops and the data will be used in combination with dietary intake data from distinct populations to assess the possible exposure levels of the trait protein from diet. The exposure is very often considered negligible because the expression levels are very low (at levels of parts per million) and the toxicity testing uses dosing levels which are normally many orders of magnitude above those in human diet.

Similarly, pesticidal proteins are assessed for their potential exposure levels to the non-target species based on their expression levels in plant tissues and on any plausible exposure of environmental species from direct consumption of the GM plant or indirect exposure via predators of herbivores that feed on the plant tissue. In addition, unlike some chemical pesticides, proteins are readily degraded in the environment either from leakage to soil or in decayed plant tissues, minimising exposure to environmental species.

Special consideration for GE crops

For GE crops, only endogenous genes are targeted for editing, and no "foreign" genetic materials are brought into the resulting crops. These genome changes could also happen under natural conditions or using conventional breeding (*e.g.*, radiation) but GE crops have more precisely controlled DNA sequence changes by design. For this reason, they are treated as conventional plants by several countries' regulatory authorities. Safety assessment then focuses on the verification that the gene editing has been restricted to the intended segment of the genome and that there has been no unintended or "off-target" gene editing. However, the regulatory landscape varies around the world. In certain regulatory frameworks, most GE crops are regulated in the same way as GM crops using a safety assessment which is similar to the one described above.

Future developments in safety assessment

For GM crop safety assessments, there are now more than three decades of extensive experience of crop cultivation and consumption. A huge body of data, evidence, experience and knowledge has been accumulated from both GM crop developers as well as regulatory authorities. Questions have been raised on how safety assessments of GM crops should be conducted in a comprehensive but more science-based way without compromising safety concerns. For example, experts from CropLife International have recommended an approach to science-based safety assessment of GM crops based on these decades of experience and also on developments in the science. For GE crop safety assessment, the same science-based guiding principles could also be applied to embrace this technology and look at what safety concerns are really necessary to be addressed.

Conclusion

With GM and GE technology applied in agriculture, innovation in plant breeding is significantly enhanced and advanced to support a more sustainable agriculture and global food and feed supply. Currently, it is still challenging to reach consensus among countries regarding how safety assessment of the GM and GE crops should be conducted due to differences in legislation and the influence of political, non-governmental organisations (NGO) and public opinion. However, with nearly 30 years of practice of safety assessment of GM crops from their developers and from regulatory scrutiny, a stepwise weight of evidence approach to assess the safety of GM crops has been very effective, with no substantial safety issue reported from commercialised GM crops. This is also critical when GE crops come into the picture, considering they are the same as those generated by conventional breeding but with more precision. There is now an opportunity to modernise the GM and GE safety assessment based on accumulated experience and knowledge and to utilise a harmonised and science-based approach.

BTS v.2, September 2025