Food Safety
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Safety Assessment Strategy for Genetically Modified Foods

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To produce food with any new technology, there must be appropriate safeguards to protect human and animal health. This includes modern biotechnology, also referred to as genetic engineering (GE) or recombinant DNA technology. Regulatory controls have been developed over the years to govern the safety assessment of genetically engineered crops or foods derived from them, commonly referred to as genetically modified (GM) foods. These controls were developed not because of identified safety problems but because of lack of previous experience with GM foods. Although many of the early concerns regarding the safety of GM foods have not materialized, they are always subjected to rigorous safety assessment procedures.

International bodies like the UN Food and Agriculture Organization and World Health Organization have long recognized that absolute safety of food is not an achievable goal. This is due to the fact that many foods and feeds contain inherent toxic substances (for example cyanogenic glycosides in cassava and glycoalkaloids in potatoes), antinutrients (for example trypsin inhibitors and phytates in soybeans) or allergens (for example in peanuts and soybeans). These traditional foods that have been consumed for millennia have not been rigorously regulated by national governments nor have elaborate procedures for safety assessments been implemented, and yet they are considered safe for human consumption.

It is generally agreed at the international level that the standard of safety that should be applied to food products derived from genetically engineered crops should be equivalent to that applied to foods and feeds derived through traditional breeding. Consequently, the safety of GM foods is in principle determined in relation to traditional foods. The goal of safety assessment of GM foods is therefore to provide assurance, in the light of best available scientific knowledge, that the food is not likely to cause harm when prepared, used and/or eaten according to its intended use. This is consistent with the safety standard that has been applied traditionally to ingredients in foods and feeds over the years whereby the objective is to establish a reasonable certainty of no harm under intended conditions of use.

The key considerations in the safety assessment of GM foods include:

- A thorough knowledge of the parent or traditional crop, and molecular characterization of inserted DNA
- Application of the concept of substantial equivalence to identify similarities and differences in composition in comparison to suitable conventional counterparts
- Evaluation of the safety of any proteins and other products expressed by the inserted DNA
- Evaluation of the nutritional consequences of the intended alterations in nutrient composition and any other alterations that are identified

The core safety assessment approach for GM crops is based on the concept of substantial equivalence. This involves the comparison of a novel crop with a suitable conventional crop that has a history of safe use. The goal is to determine whether the GM crop is substantially equivalent to the conventional crop in terms of composition, nutritional properties, toxin and allergen content, the type of processing that the crop may undergo, and the consumption by potentially vulnerable groups of people. It is important to note however that the assessment of substantial equivalence is not in itself an assessment of safety. Rather, it is a key step in the assessment process that provides a platform on which to make a comparison between the genetically engineered crop and its traditional counterpart and identify any significant differences. The concept of substantial equivalence is therefore considered the starting point of the safety assessment process.

So far, commercial GE crops have been judged to be substantially equivalent and acceptably safe compared to conventional crops by regulatory agencies in the US, Europe, Australia and New Zealand and elsewhere. However, if substantial equivalence is not established to the satisfaction of the regulatory authorities, further studies would be necessary to assess the nature and degree of risk before the product could be cleared for human consumption. The safety assessment of GE crops requires a case-by-case analysis, and the apparent safety of current crops does not guarantee that substantial equivalence will be established in future GE versions where more extensive changes in crop genetics may have been introduced.