

## How are Biotech Crops & Foods Assessed for Safety?

Commercially available foods and crops made using biotechnology have been subjected to more testing and regulation than any other agricultural products, and have all been found safe. This note is an introduction to the assessment processes that have been used in determining the food and environmental safety of these products.

### FOOD SAFETY ASSESSMENT

Although biotechnology broadens the scope of genetic changes that can be introduced into plants used for food, it does not inherently result in foods that are less safe than those produced by other techniques. This means that previously established principles for assessing food safety still apply for products of biotechnology. Moreover, these products can be judged on their individual safety, allergenicity, toxicity and nutrition rather than their method of production.



*Foods developed with biotechnology are as safe as those developed with conventional practices.*

The safety assessment of biotech foods is based on the principle that they can be compared with traditional foods that have an established history of safe use. This comparison can be based on an examination of the same risks that have been established for traditional foods, keeping in mind that many conventional foods may present specific risks depending on conditions of processing, or to individuals within a population. The intent of this comparative approach is to establish whether the new food is "as safe as" its conventional counterpart.

International discussion and expert consultations have resulted in a consensus on the specific safety issues that should be considered when evaluating these new foods. They include the following:

- **The Parent Plant:** Knowledge of the biology of the plant and its history of safe use as a food are important for understanding the natural range and variation of key nutritional components, such as vitamins and minerals; naturally occurring toxicants; anti-nutrients; and potential allergens.
- **The Gene Source:** Information about the natural history of the source organism of a new gene is important in assessing whether it could be a potential source of allergens or toxins.
- **Nutrition:** All plant breeding methods have the potential to change the nutritional value of plants or to lead to unexpected changes in levels of natural toxicants or anti-nutrients. Food safety assessments take into account the potential for any change in nutritional composition, especially in key components that have a significant impact on the diet. Laboratory analyses are used to compare the profile of the new plant with its conventional counterpart for constituents such as protein, fat, fibre, micronutrients, amino acids, fatty acids, vitamins, toxins and anti-nutrients.
- **Allergens:** The potential of accidentally introducing a new allergen (a protein that causes an allergic reaction) into a food is an important safety concern. Fortunately, food allergens have common characteristics, such as remaining stable during digestion and food processing, and they are usually abundant in foods. Internationally accepted approaches for evaluating allergenicity have been established and none of the new proteins present in biotech foods share the properties of allergens.
- **Toxins:** The possibility that new toxins may have been introduced into a food is also tested by comparing any newly produced proteins with known protein toxins using laboratory analyses and animal studies. Like allergens, protein toxins have very well characterized properties, which are not shared by any of the new proteins in biotech foods.

#### Contributors to this brief:

U.S. Agency for International Development,  
Agricultural Biotechnology Support Project  
II, and the Program for Biosafety Systems



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In assessing these safety issues, the processed version of the food and its impact on specific population subgroups, such as infants or the elderly, is also evaluated.

### ENVIRONMENTAL SAFETY

Assessing the environmental safety of a biotech plant requires an understanding of the biology of the plant itself and the practices used in its cultivation. This knowledge is important in identifying and evaluating potential environmental risks and also in designing any appropriate risk management measures. Most countries use similar environmental risk assessment approaches, which include:

- Evaluating the role of the introduced gene in the plant and any changes in the plant's characteristics
- The possible unintended secondary effects on non-target organisms
- The possibility that the modified plant could persist longer in the environment or invade new habitats
- The likelihood and consequences of the potential spread of newly introduced traits to related plants
- Potential impacts on biodiversity



*In Hebei province of China, biodiversity of insects appears to have been enhanced by the adoption of Bt cotton.*

These environmental safety concerns are not unique to plants produced using biotechnology and are also important when evaluating new varieties produced through conventional plant breeding. The objective of environmental safety assessment is to identify and evaluate any additional risks associated with the release and cultivation of these new plants in comparison with a conventional crop variety that has a history of safe use.

In addition to considering the potential risks associated with the introduction of new biotech crop varieties, consideration must be given to the risks associated with not using biotechnology to achieve desired goals. For example, the biodiversity of tropical rainforests or other ecologically sensitive areas can only be maintained if these natural ecosystems are not destroyed because of the expansion of the agricultural land base. Biotech crops can alleviate pressure to expand agricultural areas by increasing yields with improved pest resistance and increased tolerance to drought or saline soil conditions.