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Safety of Genetically Engineered Food

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What is genetically engineered food?

Genetically engineered (GE) food is produced from plants, animals, and microbes that have had their genetic code modified by the selective introduction of specific DNA segments through the use of gene splicing. This process allows the organism to acquire a desirable trait such as pest protection, herbicide resistance, or improved nutritional qualities. Foods produced through genetic engineering or containing genetically engineered ingredients are also frequently known as bioengineered or genetically modified (GM) foods. Most of our food crops have been developed using traditional genetic modification techniques through plant breeding. Today's recombinant DNA techniques allow scientists to transfer desirable traits more rapidly, predictably, and precisely than when using the traditional breeding methods. The newer genetic modification techniques also enable scientists to develop traits that could not be introduced through customary plant breeding practices.

How is the safety of GE food assessed?

While traditional approaches to assessing food safety examine the effects of individual chemicals on animal species, these methods are impractical for studying the safety of GE food. This is due to the presence of thousands of unique chemicals in foods and the inability of laboratory animals to consume large amounts of specific food items. Instead, the safety assessment of GE foods relies upon the concept of “substantial equivalence” that must be demonstrated between the GE food and its conventional food counterpart (Schauzu 2000). GE foods are considered to be “substantially equivalent” to conventional foods when levels of nutrients, allergens, or naturally occurring toxins are not substantially different and there are no new allergens or toxins detected.

It should be noted that consumption of any food—conventional, organic, or genetically engineered—may present some risk of hazard due to the presence of proteins or other naturally occurring chemicals that might cause allergies or other harmful effects. The most common allergy-causing foods are cow's milk, eggs, fish, shellfish, tree nuts, wheat, peanuts, and soybeans (Clydesdale 1996). Even the kiwi, which was introduced into the United States in the 1960s, has been demonstrated to cause allergenic reactions. As a conventionally produced food, kiwi was not tested for its allergic potential prior to its introduction into the U.S. diet. This contrasts with the scrutiny applied to GE foods, as indicated by the 2002 U.S. General Accounting Office (GAO) report concluding that all commercial GE food products produced to date in the United States have been adequately tested for safety by the U.S. Food and Drug Administration and pose no unique hazards (GAO 2002).

Which agencies regulate GE foods in the United States?

Three federal agencies regulate GE foods in this country. The U.S. Department of Agriculture (USDA) oversees environmental concerns such as field testing and the spread of genetically engineered traits to nontarget plants. The U.S. Environmental Protection Agency (EPA), according to the terms of the U.S. Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), regulates the distribution, sale, use, and



testing of plants and microbes that produce pesticidal substances such as Bt corn or Bt cotton. The EPA also regulates allowable residue levels (tolerances) for herbicide residues in areas planted with GMO-derived herbicide-resistant crops. In addition, the Toxic Substances Control Act gives the EPA authority to regulate the commercialization of genetically engineered organisms that possess pesticidal characteristics.

The U.S. Food and Drug Administration (FDA) is responsible for ensuring that foods are safe according to the requirements of the federal Food, Drug, and Cosmetic Act. This responsibility applies to conventional and GE foods alike, and the FDA has the authority to remove any food from the market that does not meet the safety standards.

The FDA uses a consultation process to work with developers of GE foods to help them meet the safety requirements. The consultation is voluntary, although the legal requirements imposed on the foods are not (FDA 1997). Presently, all GE foods that have gone to market in the United States have been submitted to the FDA's safety assessments beforehand.

If cases arise where it is determined that the GE foods might pose an increased risk of producing allergies or that levels of naturally occurring toxins are elevated relative to the levels in the conventional food, the FDA has the authority to prohibit the marketing of such foods or to limit how the food could be marketed. The EPA has similar authority in cases where genetic engineering is used to control pests or to confer herbicide resistance in food crops. GE foods containing increased levels of naturally occurring toxins or allergens are not considered "substantially equivalent" to their conventional counterparts, and require consumer labeling to indicate how they differ. Labeling is also required in cases where the genetically modified food has differences in its nutritional profile relative to the conventional food.

Are safety concerns associated with genetic engineering and StarLink corn, the lectin potato, and L-tryptophan?

One commercialized GE crop that has been subject to recall is StarLink corn. This corn variety was engineered to produce Bt, a protein from a naturally occurring soil bacterium, *Bacillus thuringiensis*, that is an effective insect control agent against lepidopteran insects such as the European corn borer. However, studies on heat stability and protein digestion indicated that a unique Bt protein known as Cry9c could not be excluded as a potential human allergen (EPA 2001). As a result, StarLink corn was initially approved only for animal consumption pending further analyses of allergenicity. Difficulties segregating feed corn from corn that could be consumed by humans resulted in small amounts of StarLink corn entering the human food supply.

The U.S. Centers for Disease Control and Prevention (CDC) received 51 reports of human illness possibly from consumption of StarLink corn, and symptoms consistent with allergic reactions to corn products were reported in 28 of the cases. Blood samples were obtained from 17 of these 28 individuals but StarLink-specific antibodies were not detected in any of the samples (CDC 2001). Analysis of corn samples provided by 10 of the individuals reporting allergic reactions indicated that nine of the samples were negative for StarLink while one sample was inconclusive (EPA 2001). Taken together, these findings strongly suggest that the Bt protein from StarLink corn was not responsible for allergic reactions in the 17 individuals studied. StarLink corn, however, was removed from the market in 2000 and the EPA concluded that the Bt protein did possess a moderate chance of causing allergies (EPA 2000).

Safety concerns have also been associated with potatoes engineered to contain a lectin gene. Lectins are considered to have potential human health benefits due to their ability to interact with carbohydrates and remove glycoalkaloids from the circulatory system. Studies performed on rats, however, suggested that the animals developed stomach damage from consuming this GE food (Ewen and Pusztai 1999).

Unfortunately, this research was limited in the number of animals involved and in the adequacy of its control studies, leaving researchers unable to draw firm conclusions about the study (Lachmann 1999). It should be noted that the specific potato product was never on the market, nor was it ever intended for commercialization. Concern for safety has likewise been linked to L-tryptophan, a nutritional supplement used to treat a variety of conditions. In 1989, 1,500 people ingesting L-tryptophan manufactured by a single Japanese company reported negative health effects, and 37 people died. While the company had previously used GE bacteria to produce L-tryptophan without incident, the outbreak of health effects coincided with the company's decision to change its manufacturing process and use a new strain of GE bacteria (Roufs 1992). The revised manufacturing process also resulted in the elimination of certain filtration steps and a reduction in the amount of active carbon used to purify the L-tryptophan. It is likely that the illnesses resulted from the presence of chemical impurities rather than the use of GE bacteria (Mayeno et al. 1994; Smith and Garrett 2005).

PERSPECTIVE

While genetic engineering of foods continues to generate concern and controversy for some consumers, evidence to date has not indicated that any foods developed for human consumption using genetic engineering techniques pose risks greater than foods produced using traditional methods. At the same time, we need to further develop and maintain scientifically based regulatory programs. Such programs must be able to flexibly and fairly assess and manage the potential risks from this evolving technology, as well as evaluate these potential risks, on a case-by-case basis.

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