Food Biotechnology: General Scientific Principles, Safety, and Regulations

The current connotation of food biotechnology—also known as Genetically Modified Organism (GMO), or Genetically Engineered (GE), among others—is a food product developed through the genetic modification of a plant, animal, or microorganism in a laboratory by scientists. However, conventional crossbreeding techniques for improving crop yield through trial and error have been used for thousands of years—from ancient civilizations to the 19th century teachings of Gregor Mendel, which led to the 20th century green revolution in which Norman Borlaug crossbred wheat varieties to avert starvation.

More recently, in the 1980s and 1990s, scientists developed new plant varieties, such as an herbicide-resistant tobacco plant that reduced weed growth without harm to the plant. The first FDA approved use of food biotechnology was the transgenic Flavr Savr tomato, which was developed in the US in 1994 to delay ripening until after harvest.[1] Over the next 20 years, food biotechnology has been used to develop many products. In 2012, more than 80 percent of US corn and cotton were developed through food biotechnology[2] with the US leading other countries.[3]

This document summarizes general scientific concepts, safety issues, and regulations relating to food biotechnology. Labeling is discussed in a separate document.

1. What is food biotechnology?

Food biotechnology is an umbrella term covering a vast variety of processes for using living organisms—such as plants, animals, microbes, or any part of these organisms—to develop new or improved food products. It includes the newer forms of food biotechnology that offer a faster and more precise means to develop food products.

2. How long has food biotechnology been in existence?

Food biotechnology is not new. For thousands of years people have been discovering that fruit juices ferment into wine, that milk can be used to develop products such as cheese or yogurt, or that beer can be made through the fermentation of malt and hops. In the 1860s, the scientist Gregor Mendel illuminated the genetic principles behind how parent plants donate certain traits to their progeny. These principles were used to breed hybrid corn, wheat, and many other crops in which certain traits could be selected in order to increase plant yield. Such

breeding methods largely accounted for the phenomenal gains in crop productivity during the 20th century and led to modern farming practices.

Today, in the arena of food, the primary goals of food biotechnology are to provide a more abundant, less expensive, and a more nutritious food supply in order to address the needs of our growing global population.

3. What are the different techniques associated with food biotechnology?

Food biotechnology techniques are often divided into old and new:

Old—Older food biotechnology techniques include conventional crossbreeding, which refers to the random recombination of genes through sexual reproduction leading to a new organism with improved traits. Crossbred plants, for instance, may require several generations to achieve a particular trait due to the randomness of gene transfer. Examples of such traits are improved crop yield, aesthetic qualities, increased tolerance to physical stress such as cold temperatures, and increased resistance to disease and insects.

New—Modern food biotechnology techniques include the joining of two pieces of DNA from different organisms leading to a single piece of DNA. Individual "specific" genes are transferred from one organism to another in order to improve the nutrient levels of a food, for example, such as fortifying a fruit or vegetable. Modern techniques are much faster and more precise. It is possible to quickly transfer a specific gene of interest rather than waiting on the random shuffling of genes over several generations.

4. What food products have been or are being developed with biotechnology?

Examples of products developed through food biotechnology include corn varieties containing a bacterial gene that kills insects and soybeans inserted with an gene that renders them resistant to weedkillers such as Roundup.[1] Cotton, squash, and papaya are other examples of commodities in which biotechnology was used to reduce pesticide use, increase profitability through greater yield, and ultimately reduce the cost of commodities at the consumer level.

Examples of foods developed through biotechnology to increase the levels of nutrients or to address a health concern include oils, such as canola, in which the levels of nutritionally essential fatty acids are increased, varieties of wheat that do not contain gluten, and potatoes (protein), kiwi (resveratrol), and lettuce (iron).[4]

5. What are some potential safety concerns associated with food biotechnology?

Questions have been raised about whether food biotechnology could introduce toxins and allergens into foods. The soybean is an incomplete source of protein for humans and animals; it is naturally low in methionine, an amino acid or protein component. In 1996, Pioneer Hi-Bred

International used a gene from the Brazil nut containing complementary levels of methionine to improve the protein quality of the soybean. An article in the *New England Journal of Medicine* demonstrated that these soybeans enhanced with genes from the Brazil nut caused allergic reactions in sensitive people.[5] Pioneer Hi-Bred International decided not to market the soybean and is looking for alternative sources of the protein.

Supporters of food biotechnology and federal regulators might see this as an example of the system at work. The soybean was tested for allergic responses before the seed went to market; when such responses were identified, the supplier withdrew the product and worked to develop a nonallergenic food.

For critics of food biotechnology, this example might reaffirm concerns, as the transfer of allergens from one food to another is no longer hypothetical. Although the fortified soybean was not marketed, concern remains.

6. How does FDA review products developed through food biotechnology?

In 1992, the US Food and Drug Administration (FDA) developed a guidance document entitled "*Foods Derived from New Plant Varieties*" that requires a food product, including those developed through food biotechnology, to be labeled if it is significantly different from what occurs in a standard product. For example, if wheat gluten was introduced into a potato, its label would require a warning for sensitive populations with celiac disease. Furthermore, FDA has developed the following assessment:

- Have the levels of any naturally occurring toxins in the plant been increased?
- Has an allergen not commonly found in the plant been introduced?
- Have the levels or bioavailability of nutrients changed?
- Have new substances been introduced into food that raise safety questions?
- What are the environmental effects?
- Have accepted, established scientific practices been followed?

More recently, in 2011, FDA released a guidance document, "*Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA."* Under the Federal Food Drug and Cosmetic Act (FFDCA), the biotechnology process to alter the structure or function of the body of an animal, regardless of the intended use of products, is considered a "new animal drug" and is regulated through similar assessments as those for plants listed in the above bullet points.

There is no absolute requirement, however, that products developed through food biotechnology undergo premarket review unless a substance was introduced into the food and is not generally recognized as safe (GRAS) per Section 409 of FFDCA. Companies are voluntarily submitting new products to FDA for review. FMI supports the FDA review process.

7. How does the EPA regulate food developed through biotechnology?

The US Environmental Protection Agency (EPA) develops standards for pesticide use and human exposure. In the case of plant biotechnology, EPA considers many factors regarding a Plant Incorporated Protectant (PIP), which is the use of biotechnology to control crop pests in lieu of a pesticide. Those factors include:

- Studies assessing risk to human health
- Studies assessing risk to non-target organisms and the environment
- The potential for gene flow (biotech crop traits transferring to non-biotech crops)
- The need for insect resistance management plans

8. How does the USDA regulate products developed through food biotechnology?

The US Department of Agriculture (USDA) regulates the products developed through food biotechnology but not the process itself. USDA's Animal and Plant Health Inspection Service (APHIS) regulates the safe introduction (environmental release, interstate movement, and importation) of plants and animals developed through biotechnology. APHIS has responsibility for assessing the ecological effects of new plants developed through biotechnology under the Plant Protection Act of 2000.

9. What has been the consumer reaction to products developed through food biotechnology?

There has been much research in numerous countries on consumer opinions regarding food products developed through biotechnology. For example, a 2003 study reports US consumers are willing to pay 15-30 percent above base price to avoid food products developed through biotechnology.[6] A 2005 study concluded that the greatest concerns of US consumers regarding food production were pesticides, hormones, and antibiotics, followed by food ingredients developed through biotechnology.[7] More recently, a report on consumer perceptions of food biotechnology showed that over two-thirds of Americans are confident in the safety of the US food supply, and that the main barrier to the acceptance of products developed through biotechnology is lack of information.[8]

Consumer awareness is on the rise, primarily due to increased media coverage and proposed legislation such as the genetic labeling Proposition 37 in California, which was not passed into law in 2012. It is anticipated that proposed legislation will continue.

10. How have consumer and environmental advocates responded to products developed through food biotechnology?

Several environmental and consumer advocacy groups believe that products developed through food biotechnology introduce food and environmental safety risks that warrant premarket testing and review. These groups are concerned with human health effects including higher risks of toxicity, allergenicity, antibiotic resistance, immune-suppression, and cancer.

The *New England Journal of Medicine's* report[5] of an allergen transferred in soybeans enhanced with genes from Brazil nuts strengthened their concerns.

Advocacy groups discuss fears of antibiotic resistance transferring from plants to human gut microorganisms through antibiotic gene markers used in the plant biotechnology process. Even though evidence of this transfer phenomenon is lacking, researchers are developing alternative methods which use metabolism markers in lieu of antibiotic ones.[9]

Environmentalists fear that more pest-resistant crops, such as Bt Corn, which is developed with the use of biotechnology to control crop pests, will lead to the evolution of highly resilient pests or weeds that pose a threat to all crops, particularly organic ones, and harm the environment. In addition, organic farmers do not want their crops cross-pollinated with crops developed through food biotechnology.

For reasons stated above, as well as others, advocates have called for a ban on products developed through food biotechnology or at least a moratorium on further development until safety and environmental issues can be more thoroughly researched.

11. What positions are other countries taking regarding products developed through food biotechnology?

The European Union (EU) has tight requirements on the approval and labeling of products developed through food biotechnology. Regulation (EC) No 1829/2003 requires a company to apply for authorization to grow and sell products developed through food biotechnology. Within 14 days of receiving the application, the national authority notifies the European Food Safety Authority (EFSA), which is responsible for performing a risk assessment within 6 months. Once approved, food and feed products developed through food biotechnology must be identified on the label. Approvals are valid for ten years.[10]

Certain jurisdictions in Japan, UK, Australia, New Zealand, and Canada also require premarket safety inspections for foods developed through biotechnology.[11]

Some countries have resorted to outright bans of GM foods. In November of 2012, Kenya banned products developed through food biotechnology. Per the cabinet, "The ban will remain in effect until there is sufficient information, data and knowledge demonstrating that GMO foods are not a danger to public health."[12]

12. What organizations are using food biotechnology in order to improve public health worldwide?

HarvestPlus, a non-profit organization supported through the Bill and Melinda Gates Foundation, donates funds for studies that use food biotechnology in order to fortify a staple crop like cassava or rice with essential micronutrients such as vitamin A, through intake of beta-carotene.[13] HarvestPlus is partnered with the Consultative Group on International Agricultural

Research (CGIAR), which is associated with government and research organizations worldwide, in the effort to use food biotechnology to reduce suffering in Africa and Southeast Asia from the inadequate intake of essential nutrients such as vitamin A, zinc, and iron.[14]

Both the World Health Organization (WHO) and the Food and Agriculture Organization (FAO), of the United Nations, assess food biotechnology as a tool that can be used to reduce hunger, improve food quality and sustainability if safety, environmental, methodology, and ethical concerns are addressed.

13. What is the grocery industry's position regarding products developed through food biotechnology?

The grocery industry believes that it is the role of the federal government to establish and enforce standards that ensure the safety of our nation's food supply. National uniformity and consistency are imperative in the development and enforcement of food safety laws governing food from production to consumption. FMI supports FDA's review process for products developed through food biotechnology. FMI policy on food biotechnology is addressed here: http://www.fmi.org/docs/policy-statements/genetically-modified-food-and-biotechnology.pdf?sfvrsn=6.

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