FDA's Role in Regulating Safety of GE Foods

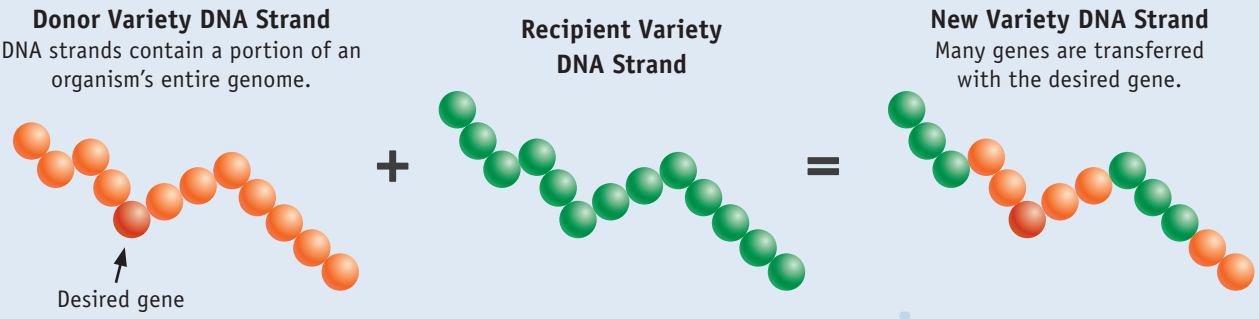
Foods from genetically engineered organisms, also known as biotech foods and referred to by some as food from genetically modified organisms (GMOs), have been in our food supply for about 20 years.

Genetic engineering refers to certain methods that scientists use to introduce new traits or characteristics to an organism. For example, plants may be genetically engineered to

Methods of Plant Breeding

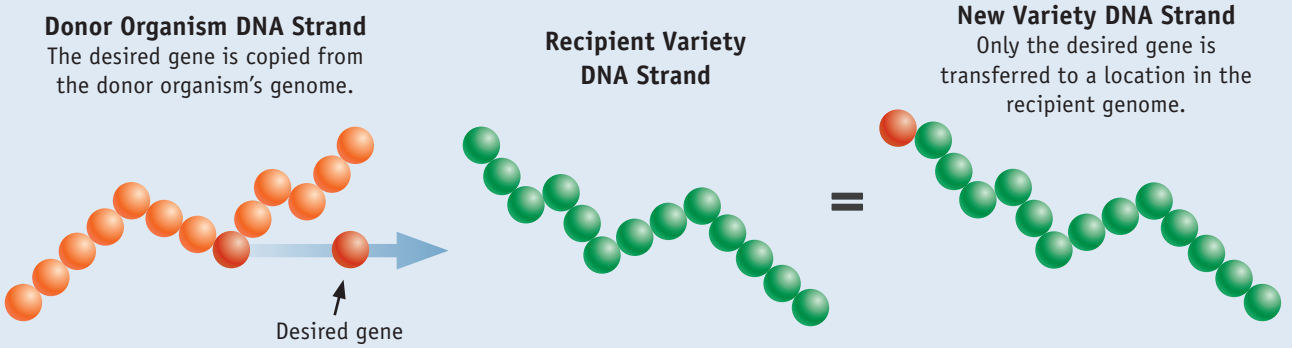
Traditional

The traditional plant breeding process introduces a number of genes into the plant. These genes may include the gene responsible for the desired characteristic, as well as genes responsible for unwanted characteristics.



Genetic Engineering

Genetic engineering enables the introduction into the plant of the specific gene or genes responsible for the characteristic(s) of interest. By narrowing the introduction to one or a few identified genes, scientists can introduce the desired characteristic without also introducing genes responsible for unwanted characteristics.



Food and food ingredients derived from GE plants must adhere to the same safety requirements under the Federal Food, Drug, and Cosmetic (FD&C) Act that apply to food and food ingredients derived from traditionally bred plants.

produce characteristics that enhance the growth or nutritional value of food crops.

Using a science-based approach, the Food and Drug Administration (FDA) regulates foods and ingredients made from genetically engineered plants to help ensure that they are safe to eat.

Since people have been modifying plants for thousands of years through breeding and selection, FDA uses the term "genetically engineered," or "GE," to distinguish plants that have been modified using modern biotechnology from those modified through traditional breeding.

FDA regulates food from GE crops in conjunction with the U.S. Department of Agriculture (USDA) and the Environmental Protection Agency (EPA). USDA's Animal and Plant Health Inspection Service is responsible for protecting agriculture from pests and disease, including making sure that all new GE plant varieties pose no pest risk to other plants. EPA regulates pesticides, including those bioengineered into food crops, to make sure that pesticides are safe for human and animal consumption and do not pose unreasonable risks of harm to human health or the environment.

In Field and Marketplace

The first genetically engineered microorganism was developed about 40 years ago; soon afterward the technology to genetically engineer plants and animals was developed. Food products made from GE microbial and plant sources have been in the food supply since the 1990s. The first food product from a GE microbe was an enzyme preparation used in the production of many cheeses.

Cotton, corn and soybeans are the most common GE crops in the U.S., according to USDA. In 2012, GE cotton accounted for 94 percent of all cotton planted, GE soybeans accounted for 93 percent of soybeans planted, and GE corn accounted for 88 percent of corn planted.

"Most GE crops are used as sources of food ingredients and as sources of animal feed," says Dennis Keefe, Ph.D., director of FDA's Office of Food Additive Safety. Corn, soybean and cotton plants—genetically engineered to ward off pests or to tolerate herbicides—are used extensively to produce food ingredients such as corn starch (in soups and sauces), corn syrup (as a sweetener) and cottonseed and soybean oil (in mayonnaise, salad dressings, cereals, breads and snack foods).

There are also new varieties of several other foods, such as squash and papayas, which are from plants engineered to resist plant diseases.

"A few plants have been engineered for nutritional traits," says Keefe. In 2012, FDA evaluated a soybean with increased amounts of omega-3 fatty acid—a polyunsaturated fatty acid that is associated with a reduced risk of heart disease.

Safety

Food and food ingredients derived from GE plants must adhere to the same safety requirements under the Federal Food, Drug, and Cosmetic (FD&C) Act that apply to food and food ingredients derived from traditionally bred plants.

FDA encourages developers of GE plants to consult with the agency

FDA supports such voluntary labeling of GE foods and has issued draft guidance on this labeling to the food manufacturing industry.

before marketing their products. Although the consultation is voluntary, Keefe says developers find it helpful in determining the steps necessary to ensure that food products made from their plants are safe and otherwise lawful.

The developer produces a safety assessment, which includes the identification of distinguishing attributes of new genetic traits, whether any new material in food made from the GE plant could be toxic or allergenic when eaten, and a comparison of the levels of nutrients in the GE plant to traditionally bred plants.

FDA scientists evaluate the safety assessment and also review relevant data and information that are publicly available in published scientific literature and the agency's own records.

The consultation is complete only when FDA's team of scientists are satisfied with the developer's safety assessment and have no further questions regarding safety or other regulatory issues.

As of May 2013, FDA has completed 96 consultations on genetically engineered crops. A complete list of all completed consultations and our responses are available at *www.fda.gov/bioconinventory*.

Views on GE foods

While FDA regulates foods and ingredients, including foods made from GE plants, the agency neither supports GE plants based on their perceived benefits nor opposes them based on their perceived risks. FDA's priority is to ensure that all foods, including those derived from GE plants, are safe and otherwise in compliance with the FD&C Act and applicable regulations.

However, FDA recognizes that there are diverse views among food manufacturers, the agricultural industry and the public.

Labeling

Many consumers are interested in knowing whether the food they serve their families is produced using genetic engineering. Food manufacturers may indicate through voluntary labeling whether foods have or have not been developed through genetic engineering, provided that such labeling is truthful and not misleading.

FDA supports such voluntary labeling and has issued draft guidance on this labeling to the food manufacturing industry (*www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm059098.htm*).

Under the FD&C Act, food labeling that is false or misleading is generally prohibited. Food labeling is misleading if it fails to reveal "material" facts—information that is material in light of statements made or suggested on the label, or material with respect to consequences that may result from the use of the food.

The agency has received two citizen petitions regarding FDA's regulation of GE foods. These petitions request that FDA change its position on the labeling of such foods. The agency is currently reviewing those petitions and considering the issues presented.

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