Regulation and Labeling of Biotech Foods

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The federal government oversees and regulates biotech plants and plant products through the United States Department of Agriculture Animal Plant Health Inspection Service (USDA APHIS), the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA). Each agency has a different role in the regulatory process.

USDA (APHIS)
This Agency regulates new plant varieties on the basis of ecological risk. APHIS determines the potential for a genetically engineered plant to pose a plant pest risk. APHIS monitors the movement of genetically engineered plants and seeds, field testing of those plants, and their destruction after testing. If APHIS determines that a genetically engineered plant does not pose a plant pest risk, then it issues a 'Determination of Non-Regulated Status' to allow for free movement and planting of the plant. This is one step required for commercialization of genetically engineered crops.

EPA
The EPA regulates pesticides and new microbes on the basis on human and ecological risk under the Toxic Substances Control Act (TSCA) and the Federal Fungicide Insecticide, Fungicide, and Rodenticide Act (FIFRA). The agency sets environmental tolerances and establish tolerances for pesticide residues in and on crops. This is to protect nontarget organisms and the environment against harmful effects. Under TSCA, the EPA reviews every applicable new chemical product before it is manufactured for commercial purposes. FIFRA controls the registration, production and use of pesticide products, including those produced through genetic engineering. After review, but prior to registration, the EPA requires that experimental use permits be obtained from the EPA for field testing bioengineered crops. EPA approval is required for genetically engineered crops producing their own plant pesticides.

FDA
The FDA regulates novel substances in foods and feeds on the basis of dietary risk. In 1992, the FDA issued guidelines that foods derived from genetically engineered plants would be regulated similar to those created those traditional methods. Federal Food, Drug and Cosmetic Act (FFDCA) requires FDA approval for food additives, whether or not they are the products of biotechnology. FDA treats substances added to food products through biotechnology techniques as food additives if they are significantly different in structure, function or amount than substances currently found in food. Products are evaluated for safety, allergenicity, and toxicity.

However, if a new food product developed through biotechnology does not contain substances that are significantly different from those already in the diet, it does not require the full food safety evaluation. Products containing non-food substances, those that are substantially different in nutrient or toxin levels, or those containing genes from sources associated with food allergies are subject to a full food safety evaluation. The FDA has the right to ban any food product, produced through biotechnology or otherwise, if determined that there is a reasonable possibility that it is unsafe.

LABELING
Because the FDA treats products derived from biotech crops similar to products produced through other means, no labeling is required just because they are products of biotechnology. However, the 1992 FDA guidelines state that labeling of foods derived from biotech crops is required if the foods

are substantially different of if they increase the risk of food-borne allergies. If any component of milk, eggs, tree nuts, legumes, wheat, fish, shellfish are transferred to a food product through biotechnology, then it must be demonstrated that the allergen is not present in the food or label the food to alert allergy-prone individuals. Currently, genetically modified foods on the market in the United States do not require special labeling to notify consumers.

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