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## WISCONSIN LEGISLATIVE COUNCIL INFORMATION MEMORANDUM

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### **Labeling Issues Related to Bioengineered Food**

#### **INTRODUCTION**

One need only open the newspaper, turn on the television or surf the Internet to discover that the labeling of bioengineered food is a public policy issue that is attracting major attention. Bioengineered foods are also referred to as genetically modified foods or “biotech” foods or genetically engineered foods.

Concerns over the potential health, environmental and economic effects of bioengineered foods have led to increased attention being focused on the labeling of such foods by state and federal regulatory agencies and has prompted introduction of federal labeling legislation in Congress.

#### **WHAT IS THE ROLE OF BIOTECHNOLOGY IN BIOENGINEERED FOODS?**

Agricultural biotechnology is a collection of scientific techniques, including genetic engineering, that are used to create, improve or modify plants, animals and micro-organisms. Scientists have used conventional techniques, such as selective breeding, to improve plants and animals for human benefit for hundreds of years. However, modern techniques now enable scientists to move genes, in ways they could not before and with greater ease and precision.

Bioengineering allows scientists to identify an individual gene that governs a desired trait, copy that gene and insert the copy into other plant

cells. Subsequent breeding and selection techniques identify the cells that successfully duplicate the desired trait and develop them into new plants for commercial use. This genetic modification can be used, for example, to create crops that grow faster, ripen slower, or better resist diseases and pests.

Many existing food products ranging from tomatoes to soybeans are being modified through bioengineering. In 1999, 90 million acres in the United States were planted with various bioengineered crops; over 1/2 of the soy bean crop and more than 1/3 of the corn crop was bioengineered.

#### **WHAT ARE THE CLAIMED BENEFITS OF BIOENGINEERED FOODS?**

Proponents of bioengineered foods claim a number of potential benefits from use and development of such products, including the following:

- Combating human diseases.
- Promoting human health.
- Combating animal diseases.
- Fighting hunger by resisting plant diseases and increasing crop yields.

- Helping the environment by reducing pesticide use.

**WHAT ARE SOME OF THE ALLEGED RISKS OF BIOENGINEERED FOODS?**

There are a number of groups and individuals who are concerned about some of the risks associated with bioengineered food. The following is a list of some of the possible negative effects of bioengineered food:

- Health impacts and allergic reactions.
- Environmental impacts.
- “Cross-pollination” with other nonbioengineered plants.
- Economic impacts; higher costs of production, separated storage and transportation.
- Costs of product recalls.
- International trade restraints and regulations.

**WHICH FEDERAL AGENCIES REGULATE AGRICULTURAL BIOTECHNOLOGY?**

The federal government has a multi-agency system to monitor and review agricultural biotechnology products in foods to assure that they are safe for the environment and to protect animal and human health. These agencies act independently:

- U.S. Department of Agriculture’s Animal and Plant Health Inspection Service (APHIS) is responsible for protecting American agriculture against pests and diseases. This agency regulates the field testing of genetically engineered plants and certain micro-organisms. APHIS also approves and licenses veterinary biological substances, including animal vaccines, that may be the product of biotechnology.

- USDA’s Food, Safety and Inspection Service (FSIS) ensures the safety of meat and poultry consumed as food.

- The Food and Drug Administration (FDA) governs the safety and labeling of drugs in the nation’s food and feed supply, excluding meat and poultry.

- The Environmental Protection Agency (EPA) ensures safe use of pesticidal and herbicidal substances in the environment and for certain industrial uses of microbes in the environment.

- The National Institutes of Health have developed guidelines for the laboratory use of genetically engineered organisms. While these guidelines are generally voluntary, they are mandatory for any research conducted under federal grants and they are widely followed by academic and industrial scientists around the world.

**WHAT ARE THE CURRENT FEDERAL FOOD LABELING REQUIREMENTS?**

The legal authority for food labeling at the federal level resides in the FDA. However, bioengineered food must be labeled as such only:

- If it is “significantly different” from its conventional counterpart.
- If its nutritional value changes.
- If anything has been added that might cause allergic reactions. This is particularly important to people with life-threatening food allergies.

The FDA has adopted, after considerable discussion, standards for foods labeled as organic foods. Under these standards, foods labeled as certified organic cannot be genetically engineered.

The FDA announced recently that it intends to pursue a more active regulatory role in the marketing and approval of bioengineered foods. The new initiatives stem in part from input the agency received during public outreach meetings held throughout the country during 1999. Specifically, under the program, foods developed using bioengineering will be subject to mandatory oversight before they reach the market, according to FDA plans announced in May 2000. The FDA's plans include a proposal to require developers of bioengineered foods and animal feeds to notify the agency at least 120 days before they intend to market the products. Consultation with the FDA has been voluntary since these foods were first marketed in the early 1990s.

Although the FDA believes that it has been consulted on all bioengineered foods and feeds currently on the market, it is proposing to strengthen the current process by requiring specific information from manufacturers. The FDA will evaluate that information in terms of product safety, labeling and alteration issues, and then provide manufacturers its conclusions about the "regulatory status" of the food or feed. The agency will post these conclusions and manufacturers' information on FDA's Web site ([www.fda.gov](http://www.fda.gov)) giving consumers access to information on individual bioengineered products.

In a related step, FDA will enhance the ability of its food and veterinary medicine advisory committees to address scientific questions related to bioengineered foods and animal feeds by adding members with agricultural biotechnology expertise.

The FDA has also indicated it plans to draft guidance standards that will assist manufacturers who wish to voluntarily label their foods as being made with or without bioengineered ingredients. The guidelines, according to the FDA, are intended to help ensure that labeling is truthful and informative.

In order to receive maximum consumer input, FDA has announced it will use focus groups to help develop the guidelines and will seek public comment on the standards.

USDA also announced that it intends to establish eight to 12 centers across the country to address regional pest management needs. These centers will help evaluate biotech products over a longer period of time, develop and share expertise, and provide information on an ongoing basis to growers, consumers, researchers and regulators.

#### **WHICH STATE AGENCY REGULATES FOOD LABELING?**

On the state level, the Department of Agriculture, Trade and Consumer Protection (DATCP) has the authority to regulate food issues and may in certain cases also enforce federal food standards and labeling requirements. DATCP also has jurisdiction over pesticide use. The Department of Natural Resources (DNR) has general jurisdiction over environmental issues in the state.

The state does not have any specific labeling requirements for bioengineered foods. However, the state has adopted a law relating to the labeling of milk and dairy products containing synthetic bovine somatotropin (rBST) or synthetic bovine growth hormone (rBGH). [See s. 97.25, Stats.] This law permits qualified milk and dairy products to be labeled with a statement that the product is "farmer certified rBST-free."

#### **PROPOSED FEDERAL LEGISLATION ON LABELING**

Federal legislation to label genetically engineered foods was introduced into both the House of Representatives and the Senate during the most recent congressional session. The bill in the house (HR 3377) was introduced by Ohio Representative Dennis Kucinich and in the Senate (S 2080) by California Senator Barbara

Boxer. The legislation (“the bill”), if enacted, would create the Federal Genetically Engineered Food Right to Know Act.

The bill requires producers and manufacturers to label all foods (not including drugs) that contain or are produced with genetically engineered material. “Genetically engineered material” is defined as material derived from a genetically modified organism. For example, foods containing genetically modified soy and genetically modified corn would have to be labeled as containing genetically engineered material.

The bill provides that foods containing milk from a cow injected with genetically engineered hormones must be labeled as produced with genetically engineered material as well. However, plant varieties developed through traditional processes, such as cross-breeding, are not considered genetically engineered.

The labeling requirements in the legislation apply if reasonably available technology can detect in the food the presence of altered molecular or cellular characteristics or if the original organism contained altered molecular or cellular characteristics.

The bill specifically provides that foods that contain genetically engineered material or are produced with genetically engineered material must bear the following label:

***UNITED STATES GOVERNMENT NOTICE:  
THIS PRODUCT CONTAINS GENETICALLY  
ENGINEERED MATERIAL, OR IS  
PRODUCED WITH A GENETICALLY  
ENGINEERED MATERIAL***

The bill contains a verification system requiring persons who have initial custody over the food to label foods they know to contain genetically engineered material. Persons who have initial custody over the food must issue a guaranty if the food does not contain genetically engineered

material. Manufacturers and retailers at later stages will not have to engage in repeat testing because they may rely on the guarantees provided. Persons holding a valid guaranty will not be subject to any civil or criminal penalties under the act if they fail to label a food later found to contain genetically engineered material. A guaranty defense already exists with respect to adulterated and misbranded food for dealers who receive an item and transfer the identical item to another person.

Farmers who plant nongenetically engineered seeds are not subject to criminal or civil penalties under the bill if surrounding crops grown from genetically engineered seeds contaminate their crops.

Finally, although the bill imposes mandatory labeling requirements, producers or manufacturers are authorized to label foods that contain or are produced with materially engineered material.

This federal legislation was not adopted during the recently completed legislative session. It is anticipated that similar legislation will be reintroduced in the next session of Congress.

**WHAT ARE SOME LEGISLATIVE OPTIONS FOR WISCONSIN?**

Among the possible legislative options available to a state are the following:

- Take no immediate action; wait to determine whether federal regulation will be adopted, as in the case of organic foods, or whether manufacturers will adopt voluntary standards for labeling.
- Direct the appropriate state agency or agencies to conduct informational hearings to gauge interest in labeling requirements for bioengineered foods.

- Initiate legislative hearings on the topic by appropriate legislative committee or committees.
- Draft legislation to allow food that does not contain bioengineered products to be labeled as such in the same manner as rBST milk is currently labeled in the state.
- Draft legislation to require any food containing bioengineered products to disclose that fact on an attached label.

Whichever option is pursued, it is clear that this issue will continue to be at the forefront of public discussions regarding food safety at the state, federal and international levels.

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The memorandum was prepared on January 17, 2001, by **Russ Whitesel, Senior Staff Attorney**, Legislative Council Staff.

For more information, check these Web sites:

- Regulatory Oversight in Biotechnology: <http://www.aphis.usda.gov/biotech/oecd/usregs.htm>.
- State Department of Agriculture, Trade and Consumer Protection: <http://datcp.state.wi.us/static>.
- For a free brochure called "Biotechnology: Enhancing Our Food Supply," send a self-addressed, stamped envelope to the International Food Information Council, 1100 Connecticut Ave. NW, Washington D.C., 20036; call 1-202-296-6540 or visit the Web site at [www.ificinfo.health.org](http://www.ificinfo.health.org).
- Genetically Engineered Food Alert, a coalition that wants more controls and safety standards on genetically engineered foods: [www.gefoodalert.org/html/whoisgefoodalert.htm](http://www.gefoodalert.org/html/whoisgefoodalert.htm).
- Physicians and Scientists for Responsible Application of Science and Technology, a group of scientists who urge more rigorous scientific study of GE foods and their long-term effects: [www.psrast.org/sitemap.htm](http://www.psrast.org/sitemap.htm).
- Biotechnology Industry Organization, an organization of the companies that develop, create and market bioengineered foods: [www.bio.org/issues.html](http://www.bio.org/issues.html).

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