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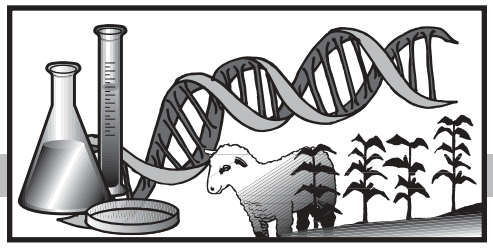

The Regulation of Biotechnology

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The products and foods derived from modern day biotechnology undergo strict governmental regulation to ensure that they are safe for humans and the environment. This publication will provide an overview of the regulations that govern biotechnology in the United States.

Regulation in the United States

Regulation of biotechnology research

In the mid-1970s, the Recombinant DNA Advisory Committee (RAC) of the National Institutes of Health (NIH) was created to provide research guidelines for the growing field of biotechnology. In 1975, a group of key scientists and policymakers met at Asilomar, California, to consider the ramifications of modern day biotechnology and to discuss ways in which regulation could be implemented. The result of these efforts was a recommended outline for the oversight of biotechnology research.

At the institutional level, biotechnology research is now reviewed and approved by individual Institutional Biosafety Committees, which have largely replaced RAC. However, RAC still plays a regulatory role in research specifically involving human gene therapy.

Regulation of biotechnology's products and foods

In 1986, the federal government completed the "Coordinated Framework for Regulation of Biotechnology," which established the policy that a product of biotechnology should be regulated according to its composition and intended use, rather than by the method used to produce it. Therefore, products of modern biotechnology are currently regulated under the same laws and policies as products created by more traditional means.

At the federal level, The Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the United States Department of Agriculture (USDA) regulate biotechnology research, product development, and approval. Regulatory authority is given to these agencies through at least 11 different laws with certain products being regulated by more than one agency. Regulated products include food, animal feeds, human and animal drugs and vaccines, cosmetics, pesticides, plant pests, and toxic substances. The development and approval process for products derived from biotechnology can take up to 10 years from the time a potential market is identified.

Regulatory Oversight of Biotechnology Products

Agency	Product Regulated
U.S. Department of Agriculture	plants, plant pests (including microorganisms), animal vaccines
Environmental Protection Agency	microbial/plant pesticides, other toxic substances, microorganisms, animals producing toxic substances
Food and Drug Administration	food, animal feeds, food additives, human and animal drugs,human vaccines, medical devices, transgenic animals, cosmetics

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Major Laws that Empower Federal Agencies to Regulate Biotechnology

Law	Agency
The Plant Protection Act	USDA
The Meat Inspection Act	USDA
The Poultry Products Inspection Act	USDA
The Eggs Products Inspection Act	USDA
The Virus Serum Toxin Act	USDA
The Federal Insecticide, Fungicide, and Rodenticide Act	EPA
The Toxic Substances Control Act	EPA
The Food, Drug, and Cosmetics Act	FDA, EPA
The Public Health Service Act	FDA
The Dietary Supplement Health and Education Act	FDA
The National Environmental Protection Act	USDA, EPA, FDA

Source: Pew Initiative on Food and Biotechnology

The USDA

The primary entity of USDA that regulates biotechnology is the Animal and Plant Health Inspection Service (APHIS). APHIS safeguards United States agriculture from pests and diseases. Accordingly, APHIS regulates the importation, interstate transport, and field testing of genetically modified (GM) plants and microorganisms. APHIS also approves and licenses veterinary biologics, including animal vaccines.

APHIS regulations require government notification before a regulated product is moved or field tested. APHIS evaluates the information in the notification and determines the safety of the proposal. Following approved testing, APHIS can be petitioned to review the resulting data in order to obtain a "non-regulated" status for the product. If a non-regulated status is granted, the product no longer requires special consideration and is ready for commercialization. APHIS reviews about 1,000 field test notifications per year for crops modified through biotechnology.

The EPA

EPA regulates the manufacture, sale, and use of pesticides to ensure that human health and the environment are protected. Because EPA limits the amount of pesticides that can be present in foods or animal feeds, it regulates GM plants that produce their own pesticides.

If EPA determines that there are no potential deleterious effects on humans, non-target organisms, and the environment, it grants permits for large-scale field tests and gives final approval for product use.

For example, scientists used biotechnology to develop corn, cotton, and potatoes that produce a protein that is toxic to certain crop-damaging insects, but is completely harmless to humans. Following government approved testing of these plants EPA determined the pesticide levels in the plants to be safe for humans and the environment.

Also, EPA oversees testing of GM microorganisms that could impact the environment upon release.

The FDA

FDA regulates all food and drugs to ensure that they are safe. Its policies subject GM foods to the same safety standards met by other foods. Because many GM foods do not differ "significantly" from their conventional counterpart, there is no requirement for pre-market approval from the FDA. However, companies do have a legal obligation to ensure that any food they sell meets the required safety standards. Therefore, most companies consider it prudent to consult with the FDA before marketing a GM food. In 2001, FDA proposed an amendment to its voluntary consultation policy with a rule that makes pre-market notification a mandatory process for all GM foods and animal feeds.

In the future, FDA will likely regulate transgenic animals and any food, drugs, or biologics produced by them.

Regulation at the state level

In addition to federal regulation, the products of biotechnology are also subject to state laws. According to the Pew Initiative on Food and Biotechnology, no state currently has more stringent requirements than the federal government, but 36 states did consider legislation that dealt with agricultural biotechnology in 2001. In Virginia, a law was passed that makes it a crime to willfully damage or destroy any agricultural product that is being tested in conjunction with a research facility. Virginia also passed a resolution establishing October as biotechnology month.

So far so good, but change may be needed

It is important to point out that there have been no confirmed adverse health effects from products of agricultural biotechnology. Thus far the regulatory system has functioned well, but future revisions may be needed as the products of biotechnology become increasingly more complex. For example, in a USDA-requested study released in February 2002, a National Academy of

Examples of Agency Involvement in Agricultural Biotechnology Regulation		
Trait	**Agency Involved in Regulation**	**Agency ensures the product is:**
Insecticide producing food crop	USDA	Safe to grow
	EPA	Safe for the environment
	FDA	Safe to eat
Herbicide resistance in food crop (i.e. Roundup Ready® soybean)	USDA	Safe to grow
	EPA	Accompanied by safe use of companion herbicide
	FDA	Safe to eat
Viral resistance in food crop	USDA	Safe to grow
	EPA	Safe for the environment
	FDA	Safe to eat
Modified oil content in food crop	USDA	Safe to grow
	FDA	Safe to eat

Source: APHIS-USDA

Sciences panel concluded that while the current system has been adequate, it is necessary to improve the testing and assessment of genetically altered crops. The study concluded that the testing of these plants should be made "significantly more transparent and rigorous" through independent reviews of all relevant data, less secrecy, and more public involvement.

Labeling, Regulation, and Acceptance of GM Products

Labeling and identity preservation

Policies concerning GM products, and GM foods in particular, vary around the world and constitute serious trade issues. In general, differing views center on the need to label GM crops and foods and the establishment of reasonable limits for how much GM material a food can contain before a label is required.

A prerequisite to mandatory labeling of GM foods is the system for "identity preservation" that would be needed to ensure that GM products are kept separate from non-GM products. Segregating crops at every step during growth, storage, transportation, processing, and exporting would be very difficult and costly to implement. Dr. Susan Harlander, a former vice president of Pillsbury Company, illustrated the situation with the following example: a medium-sized food company can have more than 6,000 products that contain 8,000 ingredients from 1,000 suppliers that move through 30 processing plants on their way to being exported to as many as 100 countries. Implementing a system to track all of these ingredients from their source (as far back as the farm) to the final destination is a daunting task that would cost billions of dollars and even then it may not be infallible.

Issues related to labeling and detection of GM material in crops and foods include:

1) the scientific methods used to screen the product;
2) the sensitivity of the detection system;
3) what would actually be detected (DNA or protein);
4) what agency would manage and regulate the testing; and
5) who would be held accountable if a product was mislabeled.

In the United States, the regulation of biotechnology products is based on the end product and not on the method used to create it. As a result, GM foods must be labeled only if they differ "significantly" from their conventional counterpart. A change is considered "significant" when there is any alteration of the nutritional content of the food or if a potential allergen is present. For example, labeling would be required if a processed food product contained soybean oil that was genetically modified to contain healthier fatty acids, due to a change in its nutritional content. A label would also be mandatory if a potato was genetically modified to contain a peanut protein that is potentially allergenic in certain people. FDA does encourage voluntary labeling of biotechnology-derived products.

In other parts of the world, policies dealing with the use of products derived from biotechnology may be similar to or much more restrictive than that of the United States. Because these policies are in a constant state of flux, it would be of little consequence to attempt to describe them in this publication.