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Domestic Regulation of Genetically Engineered Agricultural Products

Theodore Feitshans, *Extension Specialist and Lecturer*
Department of Agricultural and Resource Economics

Introduction

This article reviews the current domestic regulatory framework of genetically engineered agricultural products. Given the complexity of the regulatory system, basic knowledge for those engaged in this field is essential in order to obtain the requisite permissions to participate in research and market products, avoid regulatory fines and other sanctions, and prevent - or at least be prepared for - private lawsuits.

Since Congress has never enacted any comprehensive system for the regulation of bioengineered organisms, there is often no logic – other than history – behind the distribution of responsibilities among agencies. There is not even agreement on the terms that should be used to describe these organisms, which have been labeled *genetically engineered organisms* (GEO), *genetically modified organisms* (GMO), and *bio-engineered organisms*.

Because most regulation of genetically engineered agricultural products has been achieved under statutory authority that existed prior to the development of these organisms, jurisdiction over genetically engineered organisms is a patchwork of responsibility including several federal agencies and the states. This article will examine the role of each of the leading regulatory agencies as well as that of the states.

The Food and Drug Administration

The Food and Drug Administration (FDA) regulates all human foods (except for meats, poultry and shell eggs) and animal feedstuffs under the Federal Food, Drug and Cosmetics Act. The FDA has developed a voluntary consultation procedure for developers of food products derived from bioengineered plants. Developers are encouraged to consult early and to maintain communication with FDA personnel throughout the development process.

Prior to the marketing of a food product that is based upon bioengineered plant varieties, the product's developer is expected to participate in a final consultation with FDA. This consultation includes submission of a safety and nutritional assessment summary of the food product. If necessary, the final consultation may also include meetings with FDA scientists.

The consultation process focuses on the allergenicity and toxicity of the product. Although voluntary, no developer to date has failed to use the process. Consultation provides producers of bioengineered food and feedstuffs some protection in the event of product liability litigation.

The safety and nutritional assessment summary of the food product or feedstuff must be sufficiently detailed that FDA scientists can ascertain the approach taken by the firm to identify and address relevant issues. The information required includes the following:

- The name of the bioengineered food;
- The uses of the food and the crop from which it is derived;
- A description of the sources, identities and functions of the introduced genetic material;

- Information on the purpose of the modification;
- Information on the products produced by the introduced genetic material and the concentrations thereof in the food or feedstuff;
- Identification of known or suspected allergenicities or toxicities must be identified, as well as an explanation of the basis for concluding that the food or feedstuff is safe;
- Discussion of whether the potential for allergenic response has been altered;
- A comparison of the bioengineered product and the natural varieties of the product, with specific reference to nutritional content and any naturally occurring toxicants; and
- Any other information relevant to the safety and nutritional content of the bioengineered product.

The FDA has indicated that in the future it will publish a *Federal Register* notice making mandatory the notification of intent to market a bioengineered food or feedstuff. The Federal Food Drug and Cosmetics Act provides FDA with authority to prohibit the marketing of foods or feedstuffs deemed adulterated. Adulteration is broadly defined and may include allergenicity or toxicity introduced into a food or feedstuff as the result of bioengineering. FDA may halt marketing of such products, require recalls, and assess civil penalties for violations.

Regulation of bioengineered animal and poultry products is, for the most part, outside of FDA's authority. Meat, poultry and shell eggs are regulated by the Food Safety Inspection Service (USDA). FSIS also has jurisdiction over bioengineering of livestock and poultry products . The Federal Food Drug and Cosmetics Act does, however, provide the FDA with authority to regulate any animal or poultry drug produced through bioengineering. Regulation of bioengineered drugs is done in the same manner as for any other animal or poultry drug. In the future, when animals and poultry have the ability to produce drugs bioengineered into them, they will fall under FDA's authority to regulate drugs.

Under the Federal Food Drug and Cosmetics Act, FDA requires the pre-use approval of food additives. This does not, however, implicate food products produced from bioengineered organisms because DNA (recombinant or natural) is presumed to be "generally regarded as safe" (GRAS), and thus not an additive subject to the pre-approval process. FDA also enforces pesticide residue standards set by the Environmental Protection Agency (EPA). Enforcement of residue standards is only an issue where a regulated pesticide has been bioengineered into an organism, and that pesticide is found as a residue in food products or feedstuffs.

The U.S. Department of Agriculture

The Animal and Plant Health Inspection Service (APHIS), an agency of the USDA, regulates biological products administered to animals by authority of the Virus, Serums, Toxins Act. *Biological products* include all viruses, serums, and toxins except for antibiotics. Since biological products are regulated by APHIS, they are excluded from regulation by the FDA.

APHIS also regulates field trials of bioengineered plants APHIS maintains both telephone and e-mail hotlines that developers must use to report unauthorized releases of genetically modified organisms. All developers of bioengineered plants must obtain a permit from APHIS to move, import, or field-test such plants.

Permitting occurs either through the full permit procedure or throughnotification. Notification is a simpler, more streamlined process which developers may use to comply if the crop is one of the following: corn, cotton, potato, soybean, tobacco, or tomato. Organisms that do not qualify for notification include other crops, microorganisms, pharmaceutical-producing plants, and plants that incorporate genes that produce compounds with pesticidal properties. All of these require a full permit.

The USDA also administers the Biotechnology Risk Assessment Research Grants Program. This program's purpose is to develop science-based information about the risks associated with the development and commercialization of bioengineered organisms of all types. This is done in order to provide a sound regulatory basis to protect the public. USDA also conducts in-house research on the economic consequences of bioengineering and monitors foreign regulations and restrictions on the development and commercialization of genetically engineered organisms.

USDA's Agricultural Marketing Service pro-

vides testing services and intellectual property protection for plants propagated sexually or by tuber. Utility patent protection (the primary means of protecting inventions embodied in genetically engineered organisms) and plant patent protection are available through the Patent and Trademark Office, an agency of the U.S. Department of Commerce.

The USDA's Grain Inspection, Packers and Stockyards Administration is charged with setting up a reference laboratory for the purpose of evaluating and verifying the validity of testing procedures used to determine whether grains and oilseeds have been genetically modified. Market participants' demands that bioengineered grains and oilseeds be segregated from those that have not been modified makes this a vital program.

The Environmental Protection Agency

The EPA regulates bioengineered organisms that have pesticidal activity under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Biopesticides are subject to the full range of pesticide regulation under FIFRA. Most notably they must be effective for their intended purpose without posing undue risks to the environment.

All genetically engineered organisms with genes from more than one taxonomic genera are considered new chemicals under the Toxic Substances Control Act. Under this act, these organisms must receive pre-market review by EPA prior to their manufacture or importation.

The States

Under state pesticide and noxious weed laws, states have authority to regulate bioengineered organisms that have either pesticidal activity or the potential to become serious weeds. States may also have other laws for regulating bioengineered organisms; however, to date, most states have shown little interest to regulate under these laws.

While not regulatory in the narrow sense, bioengineering activities and products are subject to state tort laws. There have been thus far very few tort cases involving bioengineering; however, future cases involving bioengineering are likely to follow the pattern of tort cases in other industries.

The application of tort law can be divided into product liability torts and other torts. Users of defective bioengineered products may recover compensation for their damages from developers of the products, manufacturers of the products, wholesalers and retailers of the products, and others in the chain of commerce that delivered the products to the user. Product liability suits are limited to individuals who have some relationship to defendants in the chain of commerce. Under original common law doctrines, users could recover only from those with whom they had a contractual relationship. As this rule prevented recovery from most manufacturers, all states have expanded the class of user who may recover damages to include *foreseeable* users of the product.

The class of users for whom recovery is available varies greatly from state to state. States also differ in the theories of recovery available to injured users of products. All states allow recovery based upon fault (negligence). Proving fault against wholesalers and retailers usually proves difficult if their role was confined to serving as a conduit of the goods from the manufacturer to the user. For that reason many states allow the use of a strict liability theory in product liability cases. To win such a case, the user need only show that the wholesaler or retailer was the source of the product, the product was defective, and injury resulted to the user. North Carolina does not permit the use of a strict liability theory in product liability cases.

Any person injured as the result of bioengineering activities has the option of bringing a tort suit against those responsible for the injuries. These suits could potentially arise out of any phase of bioengineering including development, production, or misuse of products, and they are most likely to be based upon fault. To win a tort suit, the plaintiff must prove fault on the part of the defendant ,and that the injuries sustained were a foreseeable cause of the defendant's fault.

For example, suppose an organic producer claims that her neighbor's bioengineered crop crossbred with her certified organic crop, which rendered the crop unmarketable as an organic product. Damages would be calculated as the sale value of the organic product less the salvage value when sold on the nonorganic market. If the organic producer proves that a reasonable producer of a bioengineered crop would not allow

the spread of pollen beyond her property border; that her neighboring producer failed to meet this standard; and that the contaminant was indeed pollen from her neighbor's crop, then the organic producer may recover damages.

Whether or not a defendant has followed all applicable regulations (including voluntary standards and review procedures) is relevant to whether or not the defendant is at fault. Therefore, in order to avoid liability (as well as for the safety of neighbors and the public), it is critically important that those engaged in the development, production and marketing of bioengineered products develop programs to ensure compliance with both regulations and voluntary programs.

Conclusion

Regulation of bioengineered organisms is a divided responsibility of the FDA, the EPA, and various agencies within USDA. The states also have regulatory authority over some aspects of bioengineered organisms; however, few states have shown any inclination to exercise that authority. Organizations involved in research, development and commercialization of bioengineered organisms must take the initiative to ensure that all regulatory requirements are met. This requires close consultation with officials and scientists in the various agencies involved in the regulation of bioengineered organisms.

Disclaimer

This article in no way intended to constitute the provision of legal advice. Individuals and organizations involved in this area should seek legal advice from private attorneys with experience in the regulation of genetic engineering as well as tort law.

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North Carolina State University
Agricultural and Resource Economics
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