

## Genetically Modified Organisms: Legislative Perspectives for Animal Agriculture

Genetic modification of agricultural plants and animals promises the availability of food and fiber products with more desirable traits, such as higher quantities of vitamins or lowered amounts of saturated fats for consumers, reduced use of pesticides and other chemicals for environmentalists, and increased yields or lowered input costs for farmers. Traditional plant and animal breeding, the conventional method to modify their genes, has produced similar benefits, but recent biotechnological innovations allow scientists to select specific genes from one plant or animal and introduce them into another to confer desirable traits. Proponents argue that advances in genetics and new technologies can produce foods with greater yields and improved nutrient content to feed the growing world population in the 21<sup>st</sup> century. Critics are concerned that this technology produces uncertainties about potential long-term impacts on public health and the environment and increases problems related to trade.

Potential benefits of GMO crops are multifaceted, but initially have been targeted to the producer rather than the consumer, with the exception of the Flavr-Savr Tomato in 1994. Herbicide-tolerant and Bt cultivars of seed crops have resulted in increased yields and lowered pesticide use for these crops potentially increasing profitability and reducing contribution to water quality degradation. Increased nutritional content of foods that offer additional health benefits will be the next wave of

GMO crops. Golden rice, developed to contain high levels of carotenoid, offers hope as an effective delivery system for vitamin A deficiency. GMO crops or animal products are ideal delivery systems for vaccines as well. When the consumer observes an actual or perceived benefit from biotechnology, acceptance level is substantially increased as with the benefits of biotechnology in the pharmaceutical industry.

Some critics are concerned about genes from genetically modified plants escaping into the environment through cross-fertilization. Other concerns have been raised about the potential overuse of Bt, a natural insecticide, causing insects to develop resistance to its toxic effects. Concurrently, potential harmful effects of Bt corn on the Monarch butterfly have been a rallying point for the need for increased testing of GMO crops. In the guise of safety, increased testing on the long-term environmental and health impact of GMO crops has been suggested; however, current regulations adequately ensure human health and safety. Because the United States leads the world in privately funded biotechnology research, some suggest that foreign countries' resistance to genetically engineered crops can be traced to their desire to allow their domestic industry time to develop a competitive position in this trade. U.S. officials resisted an attempt to limit trade of bioengineered products at a meeting in Colombia in February 1999 negotiations over a "biosafety

protocol."

### Federal Regulation

**FDA:** The Federal Food, Drug, and Cosmetic Act (FFDCA) gives FDA broad authority to regulate foods by prohibiting the entry into interstate commerce of adulterated or misbranded foods. FDA has authority to inspect foods and food facilities, both domestic and imported, to ensure that they are manufactured and held under acceptable conditions and are properly labeled. In 1992, FDA determined that bioengineered foods possess the same scientific and regulatory issues as those raised by non-bioengineered foods. Thus, FDA regulates foods that have been genetically modified or engineered no differently than foods created by conventional means. The agency decided that companies developing genetically engineered foods would have to go through a special review in FDA only if

- the gene transfer produces unexpected genetic effects,
- the levels of toxicants in the food are significantly higher than those present in other edible varieties of the same species,
- nutrients in the bioengineered food differ from those in traditional varieties,
- the sources of the newly introduced genetic material come from a food plant associated with allergies,

- the food from the new variety differs significantly in composition from food of comparable varieties,
- the food contains marker genes that theoretically may reduce the therapeutic effects of clinically useful antibiotics,
- the plants are developed to make substances such as pharmaceuticals or polymers and will also be used for food, or
- the food to be used for animal feed has changes in nutrients or toxicants.

However, FDA has instituted a voluntary consultation process whereby the developer can resolve any safety or regulatory issue prior to marketing. To the extent that the agency is aware, all companies are making use of this process prior to marketing new products from engineered plants.

**USDA:** For new plants that could become pests, Animal and Plant Health Inspection Service (APHIS) issues site-specific permits for field tests or for release into the environment. The agency reviews permit applications and prepares an environmental assessment in which it evaluates the probable environmental impact of the release. The permit application process requires that the developer disclose information about the development of the plant and that appropriate facilities and control measures are in place during transport and field tests. If the agency reaches a “Finding of No Significant Impact”, a permit is issued. Before decisions are made, APHIS seeks concurrence with states on regulatory actions. For genetically engineered plants that meet certain eligibility requirements and performance standards, the sponsoring company need only submit a “notification” letter to the agency, a modified and abbreviated application that describes the gene, where the tests will take place, and the characteristics of the plant. The agency has 30 days to process the application before the sponsor can proceed with the field test. After tests are completed and an application is submitted, APHIS has 120 days to decide whether the product poses a risk of being a plant pest or whether a product is ready for full

“release” onto the market. Developers of transgenic animals must submit data to the Food Safety and Inspection Service (FSIS) to prove that the livestock and poultry involved in biotechnology experiments are not adulterated and can be slaughtered and sold as food with other beef and poultry. Prior to approving slaughter and sale, FSIS inspectors look at the number, age, sex, and other factors.

**EPA:** Plant-pesticides are regulated under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). EPA currently refers to “plant-pesticides” as plants that produce pesticides within their tissues. Although herbicide-resistant plants are not “plant-pesticides,” they are subject to EPA regulation because they can affect the use of herbicides. Under FIFRA, EPA determines the risk the plant-pesticide poses to humans and the environment and approves registration of those substances for particular uses that will not generally cause unreasonable adverse effects. This determination involves balancing risks from the pesticide with benefits associated with its use. A pesticide (including plant-pesticides) cannot be sold or distributed in the United States unless it is registered with EPA.

If the plant producing the plant-pesticide is a food crop, EPA must establish a “safe level” of pesticide residue allowed, a tolerance level, under the authority of Section 408 of the FFDCA. A “safe level” of the pesticide residue is defined as that level at which there is “a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” Because no tests of the registered plant-pesticides have shown toxicity to humans so far, EPA has exempted them from the requirement for a tolerance level.

In 1994, EPA proposed a rule to refine its regulatory oversight of plant-pesticides. As a part of the rule, EPA included in its definition both the plant-pesticide and the genetic material transferred into the plant. Under this rule, EPA proposes to exempt several categories of plant-pesticides from FIFRA and FFDCA Section 408

requirements. Under this rule, EPA proposes to exempt: (1) plant-pesticides derived from plants sexually compatible with the recipient plant, (2) plant-pesticides that act by primarily affecting the plant, and (3) plant-pesticides based on a coat protein from a plant virus. These rules will be designed to exempt certain categories of substances that EPA believes are low risk based on familiarity and presence in the food supply, e.g., plant hormones and coat proteins from plant viruses. These proposed exemptions result in little or no effects on plants produced by conventional plant breeding. The rule has not yet been finalized.

### **Proposed Legislation and GMO Labeling**

Currently, no federal agency requires foods to be labeled as genetically modified. The U.S. regulatory agencies assumed that these genetically engineered foods are similar to traditional counterparts except for the modified genes. Each agency, as with other foods, relies on industry data and rarely completes its own independent experiments comparing different foods. FDA has, however, said that it may require that all foods containing genes from commonly allergenic foods be labeled as containing potential allergens. Federal agencies focus on the end product rather than on the process by which a product is made. The framework allows the federal agency to assess scientifically whether there is a risk from a GMO food product or any new food product to human health and the environment. Recently, FDA began investigating the use of voluntary labeling for products that contain GMOs to ease tensions with trading partners, such as the European Union.

Some consumers express wariness of new “supercrops” and novelty foods, fearing that introduced genes could prove allergenic or harmful to human health. For example, if new genes inadvertently caused a plant to produce toxins at higher levels than are present naturally, there could be long-term health consequences for humans. Some consumers are worried that a gene introduced into plants to protect against pests could also cause the plant to alter its pollen, thereby

affecting the health of humans prone to some sensitivity. Others, particularly religious groups, are concerned that foods might contain genes from animals, such as swine, prohibited by some religions, and they maintain that they have a right to know if foods contain those genes. Both the kosher (Jewish) and halal (Muslim) communities have mechanisms in place to determine which products are acceptable to their adherents and, thus, have not concerned themselves with secular labeling issues. However, both Orthodox Rabbis and Muslim leaders have ruled that simple gene additions that lead to one or a few new components in a species are acceptable for kosher and halal law. The Muslim community has not yet resolved whether a gene derived from swine is an exception to the above acceptance. For example, both groups have raised no objection to the use of bioengineered chymosin (rennin) in the production of cheese. The status of more significant changes in the genetic makeup of species remains to be decided. However, cloning, in particular, raises serious ethical/moral issues for religious leaders of all faiths. That discussion has involved a much broader range of clergy within the respective communities as well as other communities without dietary laws.

The "Genetically Engineered Food Right to Know Act" bill introduced by Rep. Kucinich (OH) is broad legislation designed to require labeling of food products that contain or were produced with genetically engineered material.

Under this bill, not only would food products made directly from GMO crops be subject to food labeling, animal products derived from animals fed GMO crops or administered rDNA hormones would also be subject to labeling. However, food served for immediate human consumption in restaurants or other establishments is exempted. Although this bill is unlikely to pass, it demonstrates an increasing concern among consumers about food biotechnology because of a lack of readily available information about biotechnology. Further buried in the debate on the labeling of food containing GMO crops, are USDA's proposed National Organic Standards. Although these proposed rules would not require the labeling of food products containing GMO crops, labeling guidelines for organic products would prohibit bioengineered crops from being eligible to be considered organically grown.

The Food and Drug Administration (FDA) announced in May 2000 plans to refine its regulatory approach regarding foods derived through the use of modern biotechnology. The initiatives unveiled stem in part from input received during FDA's public outreach meetings held in 1999 during which FASS scientists testified regarding the safety of meat, milk, and eggs from food animals consuming genetically modified crops. Although the current consultative process has worked well, and the agency believes it has been consulted on all bioengineered foods and feeds currently on the market, FDA

will publish a proposed rule that specifically mandates that developers notify the agency of their intent to market a food or animal feed from a bioengineered plant at least 120 days before marketing. FDA also announced plans to draft labeling guidance to assist manufacturers who wish to voluntarily label their foods as made with or without the use of bioengineered ingredients. To receive maximum consumer input, FDA will develop the guidelines with the use of focus groups and will seek public comment on the draft guidance.

### Summary

Recombinant DNA technology is producing revolutionary changes in agriculture. This technology has numerous potential benefits including higher yields and nutritionally enhanced foods from genetically modified commodities with reduced environmental impact. Opponents of the use of rDNA technology in agriculture are concerned about possible hazards to human, animal, and environmental health, advocating more safety testing and the labeling of products. Agencies involved in regulating genetically modified foods (FDA, USDA, and EPA) are implementing policies that coordinate their regulatory activities for biotechnology products. These policies apply the same set of regulations to all food products and do not differentiate between foods that are produced with rDNA technologies and those that are produced by traditional methods.

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