

Food, Farming, and Sustainability

Readings in Agricultural Law

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on its status as a family-owned independent dairy up against a multinational corporation, held firm. The case generated a good deal of publicity and eventually settled. Oakhurst retained the right to put its Farmers' Pledge on its milk label but added a disclaimer: "FDA states: No significant difference in milk from cows treated with artificial growth hormone."

2. As a result of consumer demand, milk produced without rbST and labeled in a similar fashion is widely available, with most major supermarkets offering at least one brand. Nevertheless, some in the industry still seek to restrict the ability of dairies to segregate and label their milk in this manner. Missouri, Pennsylvania, and Ohio have all had recent laws proposed that would prohibit milk producers and processors from using labels that state the milk was produced from cows not treated with rbST.

3. The National Organic Standards prohibit the use of rbST in the production of milk that is labeled organic, as all "animal drugs, including hormones, to promote growth" are prohibited. 7 C.F.R. §205.237. Legal scholar Dean Jim Chen explores potential conflicts between the FDA's labeling policies and the National Organic Standards with respect to genetically modified foods in the article, *Beyond Food and Evil*, 56 DUKE L.J. 1581 (2007).

4. Monsanto sold its POSILAC Brand Dairy Product and Related Business to Elanco Animal Health, a division of Eli Lilly and Company in August 2008.

E. International Trade and Genetically Engineered Products

Tadlock Cowan & Geoffrey S. Becker
Agricultural Biotechnology: Background and Recent Issues

Congressional Research Report RL-32809

Feb. 13, 2009

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The U.S. approach to biotechnology regulation contrasts with that of many major trading partners. For example, the European Union (EU), Japan, South Korea, New Zealand, and Australia either have or are establishing separate mandatory labeling requirements for products containing genetically modified ingredients; in many of these countries, consumer and official attitudes toward GE foods are more skeptical. Differing regulatory approaches have arisen at least partly because widely accepted international standards continue to evolve. Incidents, such as those discussed below, have been disrupted U.S. exports and contributed to trade tensions.

GE Rice

Although several GE varieties of rice have been approved for commercial use ("deregulated," in regulatory parlance), none have been marketed, although they have been planted on test plots in the United States. In August 2006, the Secretary of Agriculture announced that "trace amounts" of an unapproved variety of GE rice had been found in samples of the 2005 crop of U.S. long grain rice. The Secretary and other USDA officials sought to reassure the rice trade and consumers that the findings posed no human health, food safety, or environmental concerns.

Owner Bayer CropScience had not asked APHIS to deregulate this particular line, called LLRICE601, which had been field tested between 1998 and 2001. Two other Bayer GE rice varieties, known as LLRICE62 and LLRICE06, had received commercial approval but have not been commercialized, USDA stated. Also, “[t]he protein in LLRICE601 is approved for use in other products” and “has been repeatedly and thoroughly scientifically reviewed and used safely in food and feed, cultivation, import and breeding in the United States, as well as nearly a dozen other countries around the world.”

Nonetheless, the discovery unsettled rice markets and rekindled longtime criticisms of U.S. biotechnology regulatory policies. The U.S. rice crop is valued at nearly \$2 billion annually. Exports represent approximately one-half or more of U.S. rice production annually on a volume basis, of which about 80% is long grain (the type in which GE material was detected), according to USDA statistics. Although the United States produces only about 1.5%–2% of the world rice crop, it was the fourth leading exporter (behind Thailand, Vietnam, and India), with more than 13% of world market share in 2005.

Of the 4.4 million metric tons (MMT) exported in 2005, Mexico was by far the leading buyer, at 753,000 MT. Japan was the second leading market at nearly 424,000 MT. Various Central American and Caribbean countries took a total of 1.4 MMT; Iraq, 310,000 MT; and European Union (EU) countries, a total of 306,000 MT, USDA data show. Much of the long grain crop is produced in southern U.S. states, which generally ship from Gulf ports to Latin America, the Caribbean, and Europe, for example. California grows mainly medium and short grain rice varieties, which are marketed in Asia, including Japan.

Following USDA's notification that U.S. rice supplies had traces of GE material, September 2006 closing rice futures dropped from \$9.70 per cwt. (100 pounds) on August 18, closing at \$8.99 per cwt. on August 25, 2005. (One year ago, the closing price was less than \$7.00 per cwt.) The European Union (EU), which bought 279,300 MT of U.S. long grain rice in 2005, reacted by adopting a measure requiring all such shipments to be tested and certified as free of LLRICE601.

Japan has indicated that it was suspending shipments of U.S. long grain rice although, as noted, most U.S. rice exports there are short and medium grain. According to a statement by the producer cooperative Riceland Foods, Inc., of Stuttgart, Arkansas, the GE material was initially discovered by one of its export customers in January 2006. Riceland then sent a sample to a U.S. laboratory, which confirmed the Bayer GE trait, which is known to be present in (and approved for) corn, soybeans, canola, and cotton. Riceland said it collected samples from several storage locations in May 2006 and found positive results that were “geographically dispersed and random throughout the rice-growing area.” Bayer was notified in early June, and its tests confirmed the presence of the GE trait in the equivalent of 6 per 10,000 kernels (0.06%).

In August 2006, USDA officials offered few additional details about the cause or extent of the problem. They indicated that they had not been informed by Bayer of the discovery until July 31, after which the Department began its own investigation, they stated. Among other actions, USDA said that APHIS was now moving to approve (i.e., deregulate) LLRICE601. Also, USDA's Grain Inspection, Packers, and Stockyards Administration (GIPSA) has verified the use of two standardized tests that can test for the GE protein in rice shipments.

Consumer and environmental advocacy groups were harshly critical of APHIS and USDA, noting that officials waited three weeks to make the discovery public—and still did not know where the samples were grown or how they entered the food supply. One group, the Center for Food Safety, subsequently called for a moratorium on all new field

testing permits until oversight can be improved. In August 2006, rice farmers in Arkansas, Missouri, Mississippi, Louisiana, Texas and California filed a class action lawsuit against Bayer CropScience, accusing the company of negligence in allowing unapproved genetically engineered rice to find its way into the commercial supply chain. By November 2006, APHIS declared the rice variety LLRICE601 safe for human consumption and deregulated the variety. USDA essentially declared that the new variety was similar to two Bayer varieties that had already been approved.

GE Wheat

Trade concerns were apparent in the debate over whether to introduce (commercialize) GE herbicide-tolerant wheat. Monsanto had asked the U.S. and Canadian governments for their approval, and other GE wheat varieties had been under development. Some producers wanted to plant the wheat as soon as it became available; others feared rejection by foreign customers of not only GE wheat, but all U.S. and Canadian wheat, out of concern that even non-GE shipments might unintentionally contain some GE grain. The latter group wanted developers and regulators to wait for more market acceptance before releasing GE wheat varieties.

In early 2003, a group of U.S. wheat producers had petitioned the Administration to conduct a more thorough assessment of the environmental impacts of the Monsanto request; 27 farm, religious, and consumer advocacy organizations endorsed the petition in early 2004. Underlining these concerns, Japanese consumer groups in March 2004 reportedly told U.S. officials in wheat-dependent North Dakota that their country would not import any U.S. wheat products if the Monsanto application was approved.

This resistance likely contributed to a decision by Monsanto to discontinue its efforts to win regulatory approval of a genetically modified wheat variety. Monsanto announced its decision in May 2004. Although Monsanto withdrew its applications for regulatory approval from EPA and APHIS, it did not withdraw its FDA application. FDA subsequently approved the application in July 2004. However, FDA approval alone is not sufficient to bring the GM wheat to market. While opposition to GE wheat remains strong among many U.S. trading partners, a spokesman for the joint biotechnology committee of the National Association of Wheat Growers and U.S. Wheat Associates, indicated in 2007 that support for planting and exporting GE wheat was growing among some U.S. wheat producers.

U.S.-EU Dispute

In May 2003, the United States, Canada, and Argentina initiated a complaint before the World Trade Organization (WTO) regarding the EU's de facto moratorium on approvals of new GE crops. U.S. agricultural interests contended that the moratorium not only blocked exports such as corn and other products to the EU, but also was fueling unwarranted concerns about the safety of agricultural biotechnology throughout the world. The United States and its allies further argued that the EU moratorium was violating WTO rules stating that a country's actions to protect health and the environment must be scientifically based, and approval procedures must be operated without undue delay.

The WTO named a panel in March 2004 to consider the case. Although the EU effectively lifted the moratorium in May 2004 by approving a genetically engineered corn variety, the three complainants pursued the case, in part because a number of EU member states have continued to block approved biotech products. In February 2006, the WTO dispute panel, in its interim confidential report, ruled that a moratorium existed, that

bans on EU-approved GE crops in six EU member countries (Austria, France, Germany, Greece, Italy, and Luxembourg) violated WTO rules, and that the EU failed to ensure that its approval procedures were conducted without “undue delay.” The final ruling was circulated to the parties in May 2006 and made public in September 2006.

The dispute panel’s ruling dismissed several other U.S. and co-complainant claims, and did not address such sensitive issues as whether GE products are safe or whether an EU moratorium on GE approvals continued to exist. The final ruling, among other things, directed the EU to bring its practices in line with WTO rules. It concluded that the EU had breached its commitments with respect to 21 products, including types of oilseed rape, maize and cotton. It also said individual bans in Austria, France, Germany, Greece, Italy and Luxembourg were illegal.

The EU initially agreed on a November 2007 deadline for compliance with the WTO dispute ruling. The parties subsequently agreed to extend the time for EU compliance with the ruling to January 2008. The EU missed this deadline in large measure. Brussels has found it hard to implement the WTO ruling because some of the 27 EU member states operate their own bans on GE crops. Individual countries (e.g., Austria, France, Greece) have prohibited the sale or cultivation of certain EU-approved varieties of GE corn (e.g., MON810, a variety produced by Monsanto). In 2008, France also initiated a temporary national moratorium on GE crops. Spain continues to dominate the EU in GE crop cultivation.

Although positive action has been slow, the United States has temporarily suspended WTO sanctions. U.S. agricultural interests, however, remain concerned that the stricter EU rules for labeling and tracing GE products will continue to discriminate against U.S. exports. If progress is not made, the issue is likely to return to the WTO’s dispute settlement body. The United States could retaliate against the EU to compensate for the annual value of lost U.S. exports, royalties and licensing fees to the EU from biotech crops. These could be levied by imposing extra tariffs on EU goods or lifting other WTO agreements regulating agriculture or health and safety.

The WTO case did not involve the EU’s new “labeling and traceability” regulations, in effect as of April 2004, to require most food, feed, and processed products from GMOs to be labeled. GE-based products also must be segregated from non-GE products, with documentation. U.S. agricultural interests argue that, even if the EU regularly approves GMOs, the labeling and traceability rules are themselves unworkable and unnecessary, and can mislead consumers by wrongly implying that GM-derived products are inherently different than non-GM foods or pose safety concerns. The EU, however, continues to defend its mandatory labeling regime. At least one EU country, Germany, has addressed the issue of potential liability from GM crops—passing a law in November 2004 that holds farmers who plant GM crops liable for damages to nearby non-GM fields (even if the GM farmers adhered to planting instructions and regulations). Some U.S. interests countered that the moratorium will not effectively end until the EU clears more of some two dozen or more GE food and agricultural products still awaiting regulatory approval—and EU member states actually implement the approvals.

The Biosafety Protocol

The Cartagena Biosafety Protocol, an outgrowth of the 1992 Convention on Biological Diversity (CBD), was adopted in January 2000 and took effect in 2003. The United States is not a party to the 1992 CBD, and therefore cannot be a party to the protocol. However, because its shipments to ratifying countries are affected, it has actively participated in the negotiations over the protocol text and in countries’ preparations for implementation.

The protocol, which 134 other nations had ratified as of August 2006, permits a country to require formal prior notifications from countries exporting biotech seeds and living modified organisms (LMOs) intended for introduction into the environment. The protocol requires that shipments of products that may contain LMOs, such as bulk grains, be appropriately labeled and documented, and provides for an international clearinghouse for the exchange of LMO information, among other provisions. The Protocol further establishes a process for considering more detailed identification and documentation of LMO commodities in international trade.

The United States objected to implementing measures approved during an international conference in Kuala Lumpur in February 2004. According to the United States, the measures would mandate overly detailed documentation requirements and potentially expose exporters to unwarranted liability damages if imported GMOs harm the environment or human health. U.S. government and industry officials believe that these and other rules could disrupt U.S. exports.

GMOs in the Developing World

In Asia, particularly China and India, governments view GMOs as a way to produce more food for burgeoning populations, despite some in-country opposition and support for labeling GE products. China has been researching GE corn, cotton, wheat, soy, tomatoes, and peppers since 1986. It has, however, been reluctant to approve commercial varieties of GE, which have been under development there. If so, it would be the first time a GE plant was used widely as a staple food, and may influence the decisions of other Asian countries with regard to accepting GE foods.

In the debate over the potential contribution of biotechnology to food security in developing countries, critics argue that the benefits of biotechnology in such countries have not been established and that the technology poses unacceptable risks. They also suggest that intellectual property rights (IPR) protection gives multinational companies control over developing country farmers. Proponents say that the development of GE technology appears to hold great promise, with the potential to complement other, more traditional research methods, as the new driving force for sustained agricultural productivity in the 21st century. They maintain that IPR difficulties have been exaggerated.

According to a recent report published by the International Service for the Acquisition of Agribiotech Applications, 12 developing nations planted GE crops in 2007. Of the total 114.3 million hectares of GE crops cultivated worldwide, 43% of the global GE crop area is in developing countries. Differences on this issue were featured in 2002, when the United Nations (UN) World Food Program (WFP) announced an appeal for food aid to meet the needs of some 14 million food-short people in six southern African countries: Lesotho, Malawi, Mozambique, Swaziland, Zambia, and Zimbabwe. However, a debate over the presence of genetically modified corn in U.S. food aid shipments made the provision of food aid more difficult and costly. Some of the countries expressed reluctance to accept unmilled GE corn on account of perceived environmental and commercial risks associated with potential introduction of GE seeds into southern African agriculture. Zambia refused all shipments of food aid with GE corn out of health concerns as well. In March 2004, Angola said it too would ban imports of GE food aid, including thousands of tons of U.S. corn, despite a need to feed approximately 2 million Angolans. The United States has blamed EU policies for southern African countries' views on food aid containing GE products. The United States maintains that genetically modified crops are safe to eat and that there is little likelihood of GE corn entering the food supply of African countries for several reasons, including the fact that current bioengineered varieties of corn are

not well adapted to African growing conditions. South Africa is the only African country to commercialize biotech crops.

The Food and Agriculture Organization (FAO) of the United Nations has also offered a qualified endorsement of agricultural biotechnology, stating that it “can benefit the poor when appropriate innovations are developed and when poor farmers in poor countries have access to them . . . Thus far, these conditions are only being met in a handful of developing countries.” Biotechnology research and development should complement other agricultural improvements that give priority to the problems of the poor, FAO said, adding: “Regulatory procedures should be strengthened and rationalized to ensure that the environment and public health are protected and that the process is transparent, predictable and science-based.” Other groups have been more pointed in criticizing GE crops, arguing that they can have hidden costs that are inadequately examined by biotechnology advocates.
