

Copyright (c) 2006 The Food and Drug Law Institute  
Food and Drug Law Journal

2006

61 Food Drug L.J. 167

**LENGTH:** 20204 words

**ARTICLE:** The International Regulation of Genetically Modified Organisms: Importing Caution Into the U.S. Food Supply

**NAME:** DEBRA M. STRAUSS \*

**BIO:**

\* Debra Strauss is an Assistant Professor of Business Law, Fairfield University, Charles F. Dolan School of Business, Fairfield, Conn. She received her B.A. from Cornell University and her J.D. from Yale Law School. Professor Strauss, a former Food and Drug Law Institute Scholar, currently teaches international business law.

**SUMMARY:**

... As such, the use of biotechnology to engineer plants, and the regulation of the resulting food crops, involves economic and trade issues, as well as science and health issues. ... The first GM crop -- the GM tomato -- was sold in the market in 1994, and genetically modified products have been commercially available in the United States since 1995. ... More stringent monitoring and labeling of GMOs in the food supply is critical for the biotechnology and food industries, as well as consumers, particularly in the area of international trade. ... Under the 1986 Coordinated Framework for Regulation of Biotechnology, three agencies primarily share the regulatory oversight responsibility for these products: USDA and its agencies, which regulate and monitor the use of biotechnology for agriculture, restricting, among other things, the addition of potential plant pests "altered or produced through genetic engineering"; the Environmental Protection Agency (EPA), which approves new pesticidal and herbicidal substances; and FDA, which has legal authority with respect to food safety and labeling. ... H.R. 4815, the Real Solutions to World Hunger Act, would restrict genetically engineered exports to GMOs approved in the United States and by the importing nation. ... The United States must address these critical environmental concerns and consumer demands through legislation and regulation to improve risk management.

...

political impact of such differences" because "food safety does not respect boundaries." <sup>n111</sup> Another goal is to instill "a much clearer degree of scientific input into the risk management measures adopted by the EU" by taking care not to avoid difficult scientific issues of risk assessment for fear of unpopularity. <sup>n112</sup> At the same time, in light of the European sensitivity to food issues and past food scares, the EFSA seeks to achieve more transparency and restore public confidence.

To this end, the Executive Director of the EFSA, Geoffrey Podger, has taken a position in favor of the labeling approach. He explains that when GM products were clearly labeled in the United Kingdom, many people bought them and initially gave GMOs a degree of acceptability, "until commodity crops starting arriving from North America in which GMO and non-GMO varieties could not be differentiated." <sup>n113</sup> The European opposition to GMOs did not come about because the science had changed, but rather it was based on ethical grounds as a reaction to being denied a choice. As a consequence, Dr. Podger believes that the solution to regaining the support of the European public is through labeling:

The great advantage of labeling is that it provides a choice. And while the people who insist on choice may be quite a small part of the population, they are very vociferous and they are often in positions of power and prominence. <sup>n114</sup>

Dr. Podger sees potential for the market for GMOs to open if these products have obvious advantages for consumers even in the face of some risk. <sup>n115</sup> Public perceptions, he notes, are open to change with new information, as long as the regulatory process is transparent and gives people all available information on the science. "Equally, of course, we are always open to new scientific evidence and to improving the regulatory process if necessary." <sup>n116</sup>

All GM products seeking to enter the EU market as food or feed must undergo an extensive authorization procedure, including a scientific safety assessment by the EFSA. As of 2000, twenty-two nations, including Great Britain, France, Australia, Japan, South Korea, and Mexico, in addition to the EU, had passed regulations that require GM food labeling. <sup>n117</sup> Thus, the EU and the international community continue to pursue an aggressive policy of caution in the regulation of bioengineered foods and food products. <sup>n118</sup>

n109 Geoffrey Podger, *European Food Safety Authority Will Focus on Science*, 5 EUR. AFF. (2004), available at [http://www.europeanaffairs.org/current\\_issue/2004\\_winter/2004\\_winter\\_77.php4](http://www.europeanaffairs.org/current_issue/2004_winter/2004_winter_77.php4).

n110 *Id.*

n111 *Id.*

n112 *Id.*

n113 *Id.*

n114 *Id.*

n115 *Id.*

n116 *Id.*

n117 See Press Release, Oregon State Univ. (OSU), OSU Economist Estimates Cost of GM Food Labels (Oct. 23, 2000), available at [http://www.biotech-info.net/label\\_cost.html](http://www.biotech-info.net/label_cost.html).

n118 See THE NATIONAL FOREIGN TRADE COUNCIL, INC., **LOOKING BEHIND THE CURTAIN: THE GROWTH OF TRADE BARRIERS THAT IGNORE SOUND SCIENCE** (May 2003), available at [http://www.wto.org/english/forums\\_e/ngo\\_e/posp47\\_nftc\\_looking\\_behind\\_e.pdf](http://www.wto.org/english/forums_e/ngo_e/posp47_nftc_looking_behind_e.pdf).

n119 United States Regulatory Agencies Unified Biotechnology Website, Frequently Asked Questions, <http://usbiotechreg.nbii.gov/FAQRecord.asp?qryGUID=2> (last visited May 13, 2006). For a compilation of the laws currently used to regulate the products of modern biotechnology and the regulations developed under these statutes (the Plant Protection Act, the Federal Food, Drug, and Cosmetic Act (FDCA), the Federal Insecticide, Fungicide, and Rodenticide Act, and the Toxic Substances Control Act), see United States Regulatory Agencies Unified Biotechnology Website, U.S. Laws and Regulations, <http://usbiotechreg.nbii.gov/lawsregsguidance.asp> (last visited May 13, 2006). See also 1986 Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (June 26, 1986).