LABELING AND TRACEABILITY OF BIOENGINEERED FOODS

Published in Economic Perspectives, an Electronic Journal of the U.S. Department of State, Vol. 7, No. 2, May 2002

(http://usinfo.state.gov/journals/ites/0502/ijee/foodlabeling.htm#dawsor)

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The United States has long been the world's preeminent leader in the development of food safety laws and regulations. In 1902 the U.S. Congress appropriated money to study the effects of chemical preservatives and colors on digestion and health. Public support for federal food and drug laws has been growing ever since.

In 1906 President Theodore Roosevelt signed the Wiley Act, making it illegal to distribute any mislabeled or adulterated foods or drugs. In 1943, in U.S. v. Dotterweich, the U.S. Supreme Court ruled that the responsible officials of a corporation and the corporation itself may be prosecuted for violations of food and drug laws. The 1954 Federal Food, Drug, and Cosmetic Act established the Delaney Clause, which banned pesticide residues or food additives that had been found to be carcinogenic in animals. President John F. Kennedy in 1962 called on Congress to develop a Consumer Bill of Rights that included the right to safety, the right to choose, the right to be heard, and the right to be informed. In 1966 the United States passed the Fair Packaging and Labeling Act, requiring that all consumer products in interstate commerce be honestly and informatively labeled. With respect to conventional foods, the Food and Drug Administration has effectively implemented this law.

The significance of U.S. leadership in food safety issues should not be underestimated, nor should the role of the United States as the world's leader and innovator in sound policies toward biosafety and consumer protection be diminished. Now more than ever, the United States should follow the path it inaugurated long ago and institute the most comprehensive and stringent regulations possible to protect the health and safety of every American, and ultimately of everyone in the world.

ENSURING ADEQUATE PROTECTIONS

With advances in agricultural biotechnology, it would behoove the United States to enhance existing food regulations and launch across-the-board pre-market safety testing, labeling, and traceability requirements for all food products and animal feed. We are at the threshold of a new era in which scientists have broken the boundaries of life forms and can extract, add, and manipulate genetic information in infinitely conceivable ways. With these abilities comes an even greater responsibility to ensure that adequate protections for the food supply are maintained and to limit the possibility of any negative

consequences that may result from the introduction of foreign genetic material. If we choose not to track the inputs and constitution of food and feed, we will not be able to correct potentially dangerous outcomes or determine sources of contamination, let alone comply with the Fair Packaging and Labeling Act.

The Codex Alimentarius Commission is the body responsible for compiling the standards, codes of practice, guidelines, and recommendations that constitute the "food code" -- or Codex Alimentarius -- for the World Health Organization (WHO) and the Food and Agriculture Organization (FAO) of the United Nations. The commission recommends that the "presence in any food or food ingredients obtained through biotechnology of an allergen" from soybeans, milk and milk products, and many other foods known to be allergenic be labeled as such. The commission also recommends that genetically modified foods be subject to risk management considerations in accordance with the draft Codex Principles for the Risk Analysis of Foods Derived from Modern Biotechnology before consideration for commercial distribution.

The standards for safety assessment are characterized by a comparison between bioengineered whole foods or their components relative to the traditionally cultivated varieties. The standards attempt to take into account both intended and unintended effects to identify new or altered hazards and changes in key nutrients. Risk management practices should, the draft standards say, at a minimum include the verification of conclusions about the absence or the possible occurrence, impact, and significance of potential consumer health effects, and should monitor changes in nutrient intake levels to determine their human health impact.

Further, the *Codex Draft Guidelines for the Conduct of Food Safety Assessment of Foods Derived From Recombinant DNA Plants* states that "animal studies cannot readily be applied to testing the risks associated with whole foods, which are complex mixtures of compounds, often characterized by a wide variation in composition and nutritional value." The guidelines continue to say that "detecting any potential adverse effects and relating these conclusively to an individual characteristic of the food can therefore be extremely difficult."

THE FDA AND SUBSTANTIAL EQUIVALENCE

In stark contrast to the draft Codex guidelines, the U.S. Food and Drug Administration (FDA) performs safety testing only on animals, particularly mice. The resulting information is used to justify the doctrine of substantial equivalence, which, according to a 1992 *Federal Register* notice, means that the FDA regulates bioengineered foods by applying rules identical to those governing plants developed by traditional plant breeding. A joint FAO/WHO report by the Expert Consultation on Foods Derived from Biotechnology in June 2000 defined substantial equivalence much differently. The report's authors concluded that the notion of substantial equivalence is only a starting point, and that "further safety assessment will be focused on establishing the safety of the differences in the new product such that the safety of the food can be established."

In 2001 the European Union (EU) abandoned the doctrine of substantial equivalence, opting for more stringent scientific risk assessment. Actions to be carried out by the new European Food Authority now cover environmental risk and human and animal health and safety, and its opinions will be shared with the public for comment. The EU then has a democratic procedure by which a majority of member states within the European Food Safety Authority Regulatory Committee vote to authorize or refuse a product.

The FDA's Voluntary Labeling Guidelines indicate that more than 50,000 comments about its policy regarding the safety and labeling of bioengineered foods have been received, and the vast majority of the comments are in favor of mandatory disclosure of genetically modified foods. The guidelines dismissed concern about the possible long-term consequences of bioengineered foods on health and the environment, concluding that "the comments were mainly expressions of concern about the unknown." That being said, the FDA's strategy for safety assessment and risk management has not attempted to substantiate the material facts of bioengineered foods and food safety. Furthermore, the FDA claims that "appropriately validated testing methods are not currently available for many foods," when, in fact, rapid quantitative tests are now common and inexpensive.

Many major U.S. trading partners have instituted labeling regimes for genetically modified foods and feed. Most notably, the European Union and China will require labeling and stringent traceability requirements, threatening the livelihoods of U.S. farmers and businesses who have already suffered as a result of the lack of regulatory oversight of biotechnology.

PRESCRIPTION FOR THE UNITED STATES

In sum, the United States should adopt a comprehensive pre-market safety testing, labeling, and traceability regime for bioengineered foods and feed to protect the health and safety of its citizenry and the environment and to ensure continued trade with our major economic partners. The United States has the responsibility to continue its leadership role in the development of sound policies for food safety around the world. In the case of genetically modified foods, the United States is quickly falling behind.

The doctrine of substantial equivalence should be abandoned, and the safety assessment and risk management strategies contained in the draft principles and guidelines of the Codex Alimentarius Commission should be formally adopted by the U.S. government and expanded upon.

Note: The opinions expressed in the article by Kristin Dawkins and Neil Sorensen do not necessarily reflect the views or policies of the U.S. Department of State.