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Toxicol Pathol 2002; 30; 132
DOI: 10.1080/01926230252824833

The online version of this article can be found at:
http://tpx.sagepub.com/cgi/content/abstract/30/1/132
Safety Assessments and Public Concern for Genetically Modified Food Products: The American View

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ABSTRACT

In the relatively short time since their commercial introduction in 1996, genetically modified (GM) crops have been rapidly adopted in the United States GM crops are regulated through a coordinated framework developed in 1992 and administered by three agencies—the US Department of Agriculture (USDA) that ensures the products are safe to grow, the Environmental Protection Agency (EPA) that ensures the products are safe for the environment, and the Food and Drug Administration (FDA) that ensures the products are safe to eat. Rigorous food and environmental safety assessments must be completed before GM crops can be commercialized. Fifty-one products have been reviewed by the FDA, including several varieties of corn, soybeans, canola, cotton, rice, sugar beets, potatoes, tomatoes, squash, papaya, and flax. Because FDA considers these crops “substantially equivalent” to their conventional counterparts, no special labeling is required for GM crops in the United States and they are managed as commodities with no segregation or identity preservation. GM crops have thus made their way through commodity distribution channels into thousands of ingredients used in processed foods. It has been estimated that 70% to 85% of processed foods on supermarket shelves in the United States today contain one or more ingredients potentially derived from GM crops. The food industry and retail industry have been monitoring the opinions of their consumers on the GM issue for the past several years. Numerous independent groups have also surveyed consumer concerns about GM foods. The results of these surveys are shared and discussed here.

Keywords. Genetically modified food; safety assessment; public concerns; regulation.

GENETIC MODIFICATION OF THE FOOD SUPPLY

We have been genetically modifying the food supply for thousands of years using classical breeding and selection as well as techniques such as radiation breeding, embryo rescue, and transposon mutagenesis. These methods create significant changes in the genetic makeup of plants and animals due to the random recombination and sorting of thousands of genes. As a result of intervention by man to domesticate plants, the original ancestor of corn, teosinte, bears little resemblance to hybrid seed corn currently grown throughout the world. Plants improved through conventional genetic modification methods undergo no formal food or environmental safety evaluation prior to introduction into the marketplace. Genetic engineering, on the other hand, allows for the transfer of a few genes in a much more precise, controllable, and predictable manner than conventional breeding, and genetically engineered crops are required to undergo extensive food and environmental safety testing before being introduced into the marketplace.

Genetically modified (GM) crops were first commercially introduced in the United States in 1996 and have been rapidly adopted by farmers. It has been estimated that 24% of the corn, 63% of the soybeans, and 64% of the cotton growing in the United States in 2001 are GM varieties. Examples of GM crops include insect-resistant (Bt) corn, cotton, potato and tomato; herbicide tolerant soybeans, corn, rice, sugar beet, flax, and canola; and, virus-resistant squash, papaya, and potato. Advantages of insect- and virus-resistant crops include improved yields and reduced use of pesticides. Advantages of herbicide-tolerant crops include improved weed control, reduced crop injury, reduction in foreign matter, reduced fuel use, and significant reduction in soil erosion. It is for these reasons that GM crops are the most rapidly adopted technology in the history of agriculture.

FOOD AND ENVIRONMENTAL SAFETY EVALUATION OF GM CROPS

GM crops are regulated through a coordinated framework developed in 1992 and administered by three agencies—the US Department of Agriculture (USDA) that ensures the products are safe to grow, the Environmental Protection Agency (EPA) that ensures the products are safe for the environment, and the Food and Drug Administration (FDA) that ensures the products are safe to eat. Rigorous food and environmental safety assessments must be completed before GM crops can be commercialized. An effective food safety evaluation system minimizes risk, but it is important to remember that food is not inherently safe. There are numerous examples of natural toxicants present in various foods (ie, solanine in potatoes and glycoalkaloids in broccoli). If we were to eliminate all foods that posed any kind of risk, our food choices would be very limited. The goal of a food safety system is reasonable certainty of no harm under normal levels of consumption. Acceptance of a new food product occurs when it is shown to be as safe as or safer than its conventional counterpart; therefore, the final assessment of safety is always comparative.

A cornerstone of the evaluation process is the concept of “substantial equivalence.” Regulatory agencies compare GM crops to their conventional counterparts. A wide range of comparisons is made including nutritional equivalency, levels of natural toxicants, and the potential for allergenicity.
in addition to a number of agronomic and environmental factors. If the GM crop is essentially identical to its conventional counterpart in all aspects, it is considered substantially equivalent and no special labeling is required in the United States. Thousands of field trials sanctioned by the USDA have been conducted in every state in the United States. FDA has reviewed fifty-one GM crops and all have been determined to be substantially equivalent to their conventional counterparts. Scientific organizations around the world agree that GM crops currently in use are not inherently less safe than conventional crops and that the types of risks for GM crops are of the same nature as conventional crops. Over 300 million acres of GM crops have been grown worldwide and there has not been a single documented adverse health affect or food safety issue associated with consumption of these products.

**GM INGREDIENTS IN PROCESSED FOODS**

Because GM crops are substantially equivalent and no labeling is required, they have been managed as commodities in the United States and have made their way through commodity distribution channels into thousands of ingredients used in processed foods. Examples of soy-derived ingredients include soybean oil, lecithin, soy protein isolates, and mono- and di-glycerides. Examples of corn-derived ingredients include corn oil, cornstarch, corn flour, cornmeal, dextrose, and high fructose corn syrup. It has been estimated that 70% to 85% of processed foods contain one or more ingredients potentially derived from GM soy or corn.

It would be extremely difficult for food companies to determine whether corn and soy-derived ingredients in their products were from GM crops. We frequently talk about the food supply chain as a linear progression from seed to ingredients used in raw grain all the way through the supply chain. This makes trace back very challenging and expensive. For example, a medium-sized food company manufactures over 6,000 processed products from over 8,000 ingredients obtained from more than 1,000 suppliers. Products are manufactured in 30 to 40 manufacturing plants and shipped to 50 or more countries.

**VOLUNTARY LABELING OF NON-GM FOODS**

As mentioned previously, mandatory labeling is not required in the United States; however, some companies have decided to voluntarily label their products as nongenetically modified. To have confidence in label accuracy, these manufacturers establish agreements with their ingredient suppliers to procure ingredients that have been manufactured from non-GM crops. This requires farmers and subsequent processors in the food supply chain to preserve the identity of non-GM raw grain all the way through the supply chain. Non-GM fields must be physically separated from GM fields in order to minimize cross-pollination. In addition, farmers need to be meticulous about cleaning farm equipment, storage facilities, and transportation equipment to minimize comingling of grain supplies. Exquisitely sensitive GM testing methods are able to detect a single kernel of GM corn in 10,000 kernels; therefore, rigorous attention must be paid to minimizing contamination. These practices need to be sustained by all subsequent handlers of the material throughout the supply chain. Chain of custody certification is required whenever grain changes hands and periodic analytical testing for the presence/absence of GM material supports these documents. There are no standardized procedures for identity preservation; therefore, each supplier must establish their own expectations with regard to purity. Food manufacturers must develop new ingredient specifications for non-GM ingredients and audit systems to ensure compliance by ingredient suppliers. It also requires that manufacturers understand the complete ingredient profile of all primary and secondary ingredients used in their products. For example, cornstarch is frequently used as a carrier of vitamins in fortified products, but may not be identified as an ingredient in the vitamin mix. All of the additional monitoring adds complexity to the supply chain and could significantly increase the costs of ingredients that will inevitably be passed on to consumers in the form of higher food prices.

Voluntary labeling also demands the availability of robust standardized and validated sampling and GM testing systems that are quantitative, reliable, accurate, and reproducible. Standardized and validated GM testing methods do not exist for the vast majority of GM products approved for use in the United States. Adventitious contamination due to cross-pollination is inevitable; therefore, quantitative assays will be required for setting tolerances or threshold levels of contamination. If a product label states, “no genetically modified ingredients,” then consumers will expect that none be present in the products. Unfortunately, the quantitative tests available today are unreliable and often result in high rates of false positives and false negatives. Authenticated reference standards are not commercially available. Each commercial testing lab has developed their own proprietary methods and every laboratory uses different methods. There is also no agreement on when to use protein versus DNA detection methods. Tests need to be simple, inexpensive, and capable of detecting GM contamination in the range of products in the marketplace. These factors create a significant challenge for any company wishing to avoid GM ingredients in their products. The lack of good GM testing methods will cause significant issues as disputes about GM status of foods arise.

The FDA recently published draft guidance on the voluntary labeling of foods containing or not containing GM ingredients. In this document, the FDA reaffirms that mandatory labeling is not required for bioengineered food, unless the food is “materially different.” For those manufacturers who would like to voluntarily label their products, the agency provides the following guidance: Labels must be truthful and nonmisleading; therefore, data will be required to substantiate label claims. The FDA provides advice on language; “genetically modified” is not recommended because this term is not technically accurate—all food has been genetically modified through conventional plant breeding. “Genetically modified organisms” is also misleading as most foods do not contain viable organisms. The FDA believes that it would be misleading to label a food as “GM-free” due to the potential for adventitious contamination from cross-pollination. They did not establish a threshold level of contamination because accurate and reliable testing methods do not exist. A statement that a food was not bioengineered or does not contain bioengineered ingredients may be misleading if it implies the...
Some companies are overtly labeling their products as GMO-free or non-GM. However, on April 5, 2001, the Wall Street Journal reported that 16 of 20 products labeled as non-GM or GMO-free tested positive for the presence of GM corn or soy. In some cases, significant contamination existed. The manufacturers of these products had received documentation from their suppliers that only identity preserved, certified non-GM ingredients had been procured. In most cases, products were not recalled because the manufacturers acknowledged the ingredients were approved for use by the FDA and there were no health hazards associated with consuming the products. The labels, however, were inaccurate and misleading to consumers. This experience illustrates that even under best-case scenarios, it is very difficult to guarantee that the non-GM label is truthful.

The majority of food companies are not avoiding GM ingredients for products marketed in the United States. They have confidence in the safety of GM crops and in the regulatory processes used to evaluate food and environmental safety. Because GM crops have been readily adopted in the United States, availability of non-GM crops has been limited and these ingredients are more expensive. The food industry would need to be able to accurately forecast their supply needs for non-GM ingredients so farmers could be instructed on the quantities required. In addition, the food industry lacks separate storage, processing, labeling, and transportation capabilities required to ensure separation of GM and non-GM raw materials and final products. There is little confidence in the adequacy of current GM sampling and testing methodology to substantiate label claims and there is significant liability if label claims are inaccurate. Finally, the food industry hopes that the next generation of bioengineered products will deliver compelling consumer benefits.

THE NEXT GENERATION OF GM FOODS

The next generation of GM foods will focus on traits that provide tangible and consumer relevant benefits. Biotechnology can be used to remove allergens, natural toxicants and antinutrients from foods such as peanuts, soybeans, rice, and wheat. Taste, texture, aroma, ripening time, and shelf life of fresh fruits and vegetables can be improved. It will be possible to improve the nutritional quality of foods. Examples include modification of the saturation level of oils to produce products high in mono-unsaturated fatty acids that are more stable, resist oxidation, do not require hydrogenation, and reduce cholesterol levels when consumed. It is possible to increase the content of Vitamin E, a natural anti-oxidant, and to insert the capability of producing plant-based omega-3 fatty acids into oil seeds. Biotechnology can be used to elevate levels of Vitamins A, C, D, and folate, increase anti-oxidants, and enhance iron bioavailability in vegetables, fruits, and grains. It is also possible to increase the level of various phytochemicals in plants that have been associated with disease prevention such as lycopene in tomatoes and sulfurofane in broccoli for reducing cancer risk, lutein in vegetables for reducing risk of macular degeneration, and so on. The advancing fields of human and plant genomics and proteomics will identify additional plant-based compounds that could have a positive impact on human health. These are the kinds of products that excite food companies and ultimately consumers in the future.

The future of agricultural and food biotechnology will depend on a number of factors including continued grower support, food industry and retailer unanimity in policies regarding the use of GM ingredients, government consistency, documentation of tangible consumer benefits without undue risk, and consumer education and acceptance. Additionally, until there is international harmonization on GM foods, turmoil in the marketplace will continue. Without consumer acceptance and a coordinated approach across all segments of the food supply chain, the promises of agricultural and food biotechnology could be unfulfilled.

Food companies would respond and offer non-GM products if they were convinced there was market demand and that consumers would be willing to pay a price premium to cover the increased costs for identity preservation and testing.

Consumers tell us that simply labeling products containing GM ingredients does not provide enough information. They are interested in how the product was modified and the benefit associated with the modification. Food companies would be challenged to adequately explain all of this information on the label. Consumers also indicate instead of labeling GM ingredients on food labels, more information could be provided through toll-free numbers, point of purchase brochures, and web sites (News releases at http://www.iflic.org).

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