

POINT-COUNTERPOINT

neering applied within the food system. To support human health and the health of our natural ecosystem, we will pursue secure, sustainable, equitable food systems—locally and globally (1,2).

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Food biotechnology in the new millennium: Promises, realities, and challenges

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Biotechnology is not new; it has been used for centuries in food processing (eg, beer and wine making) but only recently has it gained media attention as a process to manipulate or insert foreign DNA into bacteria, plants, and animals. The era of genetic engineering (GE) began in the early 1970s when California scientists discovered how to make recombinant DNA (rDNA) using restriction enzymes to cut and paste DNA. Recombinant DNA and related GE techniques allow the transfer of genetic material across species barriers giving a bacterium, plant, or animal a trait that it does not possess naturally. The first generation of GE foods has been

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geared mostly toward the production of crops engineered for disease and insect resistance to prevent crop losses; and the production of herbicide-resistant crops, which allow farmers to spray broad-spectrum herbicides over growing crops, making weed management easier. Transgenic crops were first planted commercially in the growing season of 1995. Since then, their use has increased rapidly. By 1999, 70 million acres were planted in the United States alone, and a total of 98.6 million acres were planted globally (1). Examples of currently approved GE crops in the United States include glyphosate-resistant soybeans, insect-resistant corn and potatoes, and virus-resistant squash (2).

Biotechnology proponents promise that the second generation of GE foods and crops will provide consumers (and farmers in developing countries) with more direct benefits. In

developed countries, scientists hope to create healthier foods such as cereal grains with increased amounts of soluble and insoluble fiber; milk with improved calcium bioavailability; and vegetables with boosted levels of antioxidants (3). In developing countries, public sector agricultural biotechnology research could contribute to improved yields for poor farmers and more plentiful, affordable, and nutritious food for consumers worldwide (4). Although proponents claim GE foods and crops have many potential benefits — from a healthier food supply to improved crops yields and decreased pesticide use— more and more controversy is being generated worldwide as to whether or not GE foods and crops are safe for human consumption and the environment. Much of the controversy stems from disagreement over how GE foods and crops should be regulated, including whether or not individual countries have the right to refuse GE foods and crops they believe are unsafe for the environment or inadequately tested; and if GE foods should be labeled. Such disagreements also are rooted in different cultural approaches to risk acceptance and management (5). The purpose of this commentary is to further explore the current controversy surrounding GE foods and crops.

THE QUESTION: HOW TO REGULATE GE FOODS?

Much of the controversy over GE foods in the regulatory arena is related to whether or not the concept of “substantial equivalence” should be used to guide regulatory policy. In 1992, the Food and Drug Administration (FDA) adopted regulatory policy that specified foods produced through GE techniques or containing genetically modified (GM) substances substantially similar in “structure, function, and composition” to substances already in the food supply (proteins, carbohydrates, fats, or oils) as “generally recognized as safe” (GRAS) (6). This terminology was later changed to “substantially equivalent” (SE) (7). Because such products are deemed GRAS or SE, they are not required to undergo mandatory pre-market approval. However, if the intended ‘expression products’ (proteins, carbohydrates, fats, or oils) differ significantly in structure, function, or composition from substances ordinarily found in food or have no history of safe use, GE foods may not be considered GRAS, and may have to undergo food additive regulation. The FDA generally agrees that most substances currently being introduced into food by genetic modification are believed to be substantially similar or SE to those already introduced into the food supply through other means. Guidelines for companies to engage in a voluntary consultation process with FDA were published in 1997 (8).

Several public interest groups and scientists formally have expressed dissatisfaction with the FDA’s current regulatory policy on GE foods (9-13). They believe using a GRAS or SE designation as the basis for food safety evaluation cannot accurately predict potential allergenicity and toxic effects since the function of a food-producing organism could be altered, causing it to produce new allergens or increase the expression of allergenic proteins already present. Other scientists believe that SE is not an acceptable basis for evaluating the second generation of GE foods, which promise to bring more complex foods to the marketplace (14). Scientists generally agree that currently available testing methods may not accurately predict the allergenic potential of foods engineered using proteins from sources of undetermined allergenicity, which have not previously been a component of the food supply (11-20). This issue was highlighted in a recent National Re-

search Council (NRC) Report on Genetically Modified Pest-Protected Plants (20):

“FDA should put a high priority on finalizing and releasing preliminary guidance on the assessment of potential food allergens, while cautioning that further research is needed in this area...for example, the committee learned of one transgenic pest-protected plant that contains an insecticidal protein that has a key biochemical characteristic of food allergens: stability in simulated gastric juices. Crops containing this protein are currently restricted to use as animal feed. Tests that the manufacturer should conduct to evaluate the potential allergenicity of this protein are not well defined, and both EPA staff and the manufacturer would benefit from guidance from FDA.” (p 169)

The FDA recently announced plans to modify its review of GE foods by requiring companies to notify the agency of their intent to market a new GE food at least 120 days prior to marketing; specific information on GE products also must be submitted by manufacturers (21). Certain public interest groups believe that requiring companies to engage in mandatory consultations with FDA falls short of the mandatory pre-market testing required for food additives (22).

A second controversy surrounding GE foods stems from whether or not consumers have the right to know if their food has been bioengineered. Current FDA regulatory policy for GE foods does not require mandatory labeling for GE foods because it believes the method of development or process used in producing a crop is irrelevant information for disclosure in labeling (6). Some consumer groups and legislators believe that consumers do have the right to know if their food has been bioengineered (10,22,23). Labeling of GE foods may be needed for adherence to cultural or religious beliefs (10,24). Others have justified labeling by arguing that there is a need to base policies on the precautionary principle, where it is acknowledged that not enough is known about the long-term effects of GE foods and crops on human health (11, 13, 25). The FDA has announced plans to draft guidelines for assisting natural food product manufacturers who want to label their food “GE Free.” The agency also has said it will provide assistance to companies who wish to label their products as containing GE ingredients (21). However, because very few companies, to date, have labeled their products as containing GE ingredients, certain groups believe that guidelines for voluntary labeling will not adequately assist consumers who want to know if their food has been genetically engineered (23,26).

Two “right to know” bills—HR 3377 (House of Representatives) and S 2080 (Senate)—have been introduced into Congress that, if passed, would require any GE food to bear the graphic of a double helix and the following text: “United States Government Notice: This product contains genetically engineered material, or was produced with a genetically engineered material.” Thus far, each bill has gained some Congressional support; however, there has been heavy opposition to both bills from industry lobbying groups (eg, Grocery Manufacturers of America, National Food Processors Association) who believe the use of such labels would only serve to confuse consumers. Mandatory labeling of GE foods already is required in Europe, and other countries such as Australia, Japan, New Zealand, and South Korea will be implementing mandatory labeling in the near future (23).

At the international level, controversy has stemmed from whether or not a legally mandated United Nations sponsored Biosafety Protocol, as commissioned by article 19 of the Convention on Biological Diversity (CBD), is needed to regulate genetically modified organisms (GMOs) introduced into the environment. The treaty, which is based on the precautionary principle, gives countries the right to bar imports of GM seeds, microbes, animals, and crops seen as a threat to their environment. Exporters also are required to obtain an importing country's approval through a procedure known as advance informed agreement (AIA) for initial shipments of GMOs for release into the environment. GMOs intended for food, feed and processing are exempted from the AIA requirement; however, these shipments must be labeled "may contain" GMOs, and countries can decide whether or not to import those commodities based on a scientific risk assessment. New negotiations will be launched to address the issue of liability for any damage resulting from the cross-border movement of GMOs. The new treaty, recently approved by over 130 countries, will formally go into effect after being ratified by 50 countries (27). Although there are those who disagree (28), many scientists agree that such a protocol is needed to prevent further damage to the Earth's ecosystem (29-33).

RISKS AND CONCERNS

Public concern about GE foods and crops appears to be influenced by many factors: animal and human health risks, environmental and ecological impacts, ethical issues, and social, economic, and control issues that need to be acknowledged (ie, intellectual property rights, globalization, questions about who is driving the R&D agenda, distribution of costs and benefits, and impacts on corporate structure and control) (34). Below, I will address what I consider to be several of the most important concerns from an ecological perspective.

Environmental/Ecological Impacts

Many scientists have expressed concern regarding the potential environmental and ecological impacts of GMOs (12,24-33,35-40). The nature of the risks presented by GMOs will vary with the type of organism released. One area where scientists have expressed concern is the development of transgenic fish (12,30,33). Muir and Howard (41) have demonstrated that manipulating genes in Japanese medaka fish to select for body size reduced their reproductive fitness. These researchers estimated that the release of even one GE fish could lead to local extinction of the species within 37 generations. Another concern is that insects, which feed on cotton, corn, and other crops, may eventually develop resistance to the naturally occurring insect toxin *Bacillus thuringiensis* (Bt). Some scientists worry that such failures will speed up the evolution of pests resistant to Bt. Once resistance develops, the use of Bt will be lost to farmers, including many organic farmers, who use the natural insecticide in spray form to control pests (42). Several recent studies suggest that pollen dispersed from Bt corn may cause damage to non-target organisms (43-47). However, because such results are preliminary, further field-based research is needed to determine if Bt pollen dispersed from transgenic crops could have detectable effects on the population dynamics of non-target organisms (20). More recent studies suggest that Bt toxins may be protected from biodegradation and persist in the soil (48,49). Certain scientists have called on the government to design new protocols for

identifying the long-term risks of GE crops to non-target organisms, including soil ecosystem impacts and effects of Bt toxins on beneficial organisms (50). A NRC Report on Genetically Modified Pesticide-Protected Plants also has recommended the need to (20):

"monitor ecological impacts of pest-protected crops on a long-term basis to ensure the detection of problems that may not have been predicted from tests conducted during the regulatory approval process." (p. 10)

Some scientists believe the most significant ecological risk in releasing GE crops into the environment is that they may transfer their newly acquired genes via pollination to wild relatives. Such gene transfer is likely to occur when GE crops are grown in a crop's geographical center of origin where wild ancestors are growing nearby or have been introduced along with the crop. Because many of the world's major crops originate in developing countries, gene transfer will be more of a problem for developing countries than developed ones. However, there are exceptions, including virus-resistant squash, which some scientists believe will transfer its virus-resistance genes to wild squash, a native to the southern United States, making it a hardier, more abundant weed (20,30).

From an ecological standpoint, one of the most questioned applications of GE is the development of herbicide-resistant crops (HRCs). Some scientists believe HRCs will decrease herbicide use by allowing a single application of a broad-spectrum weed killer to replace two to four applications of other products (51). Other scientists, however, believe HRCs will increase herbicide use and reliance, and accelerate the emergence of resistance (37-38). A recent analysis of United States Department of Agriculture (USDA) herbicide-use data has shown that farmers growing Roundup Ready™ (RR) soybeans used two to five times more herbicide measured in pounds per applied acre, compared to other popular weed management systems used by soybean growers not planting RR varieties (52). The choice of herbicide-resistance as industry's main target for engineered crops appears to be driven by efforts to simplify weed management for farmers and hold or win the herbicide market share.

PUBLIC PERCEPTIONS

Current public opinion polls reveal that consumers find certain applications of biotechnology and GE more acceptable than others (53-59). Consumers would be more likely to buy bioengineered foods that taste better or fresher (54%); protect against insect damage or require less use of pesticides (69%) (59); do not involve harm to animals; and do not involve the transfer of animal genes into plants (53,54). Lack of consumer acceptance of GE foods and crops is often attributed to the public's ignorance or misunderstanding of science, which can be remedied through massive educational campaigns (58). An alternate view is that lack of consumer acceptance, in many cases, stems from a lack of trust between the public and other sectors of society (5,60). In one consumer survey, only 11% of respondents reported trusting information on food biotechnology supplied by industry (54). Certain surveys also suggest consumers are skeptical about the government's ability to regulate biotechnology (61).

In a recent survey, a majority of consumers (56%) reported wanting a range of information about GE foods, including tests focusing on their long-term effects, and more specifically,

what, if any, consumer risks are involved. An overwhelming majority of persons (86%) said they wanted GE foods sold in stores to be labeled (62). This finding confirms results from other opinion polls and surveys that demonstrate consumers' desire for labeling of GE foods in the marketplace (53,57;63-66). One way to resolve this controversial issue would be to provide consumers with balanced information on the potential benefits and risks of GE foods, and then allow consumers to make their own informed choices. Labeling also could function as an important tool for building trust between consumers and producers (60). As stated by Nestle (67),

"The labeling issue is really this simple: consumers are more likely to buy the food products of biotechnology if they think the foods are worth the price and they trust the producer. Trust requires disclosure." (p. 1056)

IMPLICATIONS AND RECOMMENDATIONS

If GE foods and crops are to be acceptable to consumers, the following steps must be taken in order to bring the promises of biotechnology more in line with reality. First, biotechnology companies need to develop more GE foods with direct benefits to consumers. Second, to ensure these benefits, more effective regulatory policy is needed, including mandatory pre-market testing and labeling. Third, if companies are producing beneficial, safe, and ethical products, they should encourage the public to purchase them through labeling (68). Labeling is an important tool for building trust between consumers and producers that would give consumers the choice as to whether or not they want to purchase such products. Fourth, if modern biotechnology is to contribute to sustainable agricultural development, the International Biosafety Protocol must be adopted. Such a protocol will help ensure that poor farmers and consumers are able to reap the benefits modern biotechnology may have to offer and profits generated by biotechnological research and development are invested in the conservation of the habitats that produced it. Finally, if the potential of small farmers is to be realized, research of, and investments in, alternatives, such as ecosystem-based agricultural techniques, are needed (69,70).

Consumers perceive nutrition and dietetics professionals as a trusted source for food and nutrition information, including information on biotechnology (53). In order to maintain consumers' trust, we, as professionals, must understand and respect their needs, concerns, and value systems regarding GE foods. Education that outlines benefits and risks, as well as the social, economic, and ethical issues surrounding GE foods, will help ensure that a well-rounded, balanced view of this technology is transmitted to consumers (71). Furthermore, education should not only be framed as a one-way exchange of knowledge where consumers are perceived as passive receivers of information. Rather, nutrition and dietetics professionals should engage in a broader dialogue with the public about what the future food system should look like.

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