

# **The Interplay of Public Perception Issues and Federal Regulatory Policy in Agricultural Biotechnology: A U.S. Perspective**

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## **Introduction**

Promise of positive impact exists for the new genetic technologies in terms of modifying agricultural crops to create more affordable and nutritious food and feed sources in a more environmentally friendly manner. As with other new technologies, however, come questions about whether the regulatory mechanisms that are in place adequately protect and insure consumer and environmental safety. In the U.S. extensive governmental policy and infrastructure were formulated and continue to be refined to govern the development and release of the products of biotechnology. These policies have focused on scientific consideration of consumer and environmental safety issues but also embrace issues relating to public acceptance by attempting to address consumer concerns.

A portion of the unrest about genetically engineered foods derives from the fact that, unlike earlier in the century, the majority of the population is no longer connected to farming. For this reason many consumers do not appreciate the problems faced by those who grow, harvest, ship and process our food. An appreciation of the environmental cost of the food production system in developed countries is often lacking and therefore comparison of the impact of a new technology is often inaccurate. It is also often difficult for those in developed nations, who worry more about the price of food than its availability, to fathom the need for devising methods for more efficient food production methods in developing countries. Without an appreciation for such matters, it might be difficult to understand why new technologies would be advantageous for the production of the foods of tomorrow. Consumers, and even producers, often do not understand how these foods will be similar to or different from the foods of the past. Because of this lack of familiarity judging the safety and impact of these crops becomes more problematic.

More recently the turmoil in Europe over the field testing and import of genetically engineered foods has focused on other issues relating to consumer acceptance, some peculiar to the situation in Europe. Many consumers in Europe do not feel confident that their regulatory system adequately protects the consumer. Also, there are fundamental economic issues that influence attitudes. Most genetically engineered crops are being grown in the U.S., and, by being forced to accept these imports since such crops cannot be grown in Europe, the European markets become even more dependent on U.S. imports. Lastly, the new paradigm for agriculture, resulting in part from the cost of the development of the new biotechnological methods, leads to the situation where the development, deployment and production of food is largely controlled by a handful of multinational companies. This type of control, unparalleled in the history of agricultural production, is unsettling to both those involved in food production as well as those who consume the food that is produced. To many this situation spells "out of control"; multinationals control what we grow and what we eat and this is unsettling and unfamiliar.

## **Discussion**

### *History of Food Development*

Since the time when humans moved from a nomadic lifestyle into one characterized by the exploitation of native plant and animal life, humans have modified and improved their foods. The classical breeding methods that were used have continued to the present and are now with increasing frequency augmented with other technologies, including the use of molecular techniques. These

newer techniques, although similar in biochemical mechanism to the classical methods, have some significant differences from the time-honored methods. First, the modern methods permit the genetic content of target organisms to be manipulated in a very precise manner, involving in many cases changing one gene amongst the over 100,000 genes present in the plant. In addition, the source of the gene can be any other living organism, whereas the older methods required that the two organisms exchanging genetic materials be closely related, usually members of the same genus or species.

#### *Establishment of Regulatory Policy.*

Consumers in the U.S., Europe and Japan take for granted that the foods created by the classical methods, which they purchase although with few exceptions do not produce, are safe for themselves and their families. They involve very low risk of acute food-borne illness. However, safety and zero risk are not the same. What individuals define as "safe" is, for them, "acceptable risk" and cannot be determined scientifically. Individuals and societies can decide the level of risk they are willing to accept in their foods and what regulatory policies are necessary to insure the agreed-upon level of risk. It is important for scientists to realize that, while risk can be scientifically estimated, safety is a matter of public definition and is outside the realm of science. How should public policy be determined when public perceptions of risk are at odds with scientific assessments? Which should be given priority? The answer lies somewhere between the two extremes. Public concerns must be taken seriously when they are widespread and persistent. This opinion must be tempered with the scientifically determined degree of risk. Policy that ignores scientific assessments will not serve the public good, but it cannot be the only guiding principle.

#### *Scientific Risk Assessment versus Perception of Risk*

Using scientific information, the potential for food safety risk in genetically engineered foods can be fairly accurately determined; this assessment has formed the basis for certain aspects of U.S. regulatory policy. However, the public's perception of risk, often inconsistent with the scientific measurement of risk, has also influenced regulatory policy. The basis for this concern depends on the familiarity, "friendliness" and voluntary nature of the risk. Compare the adverse consumer reactions to bovine spongiform encephalopathy (BSE)-tainted beef or dioxin-tainted pork, beef and poultry in the EU to the willing acceptance by many of the risks of cigarette smoking or by a few of the dangers of picking their own wild mushrooms or consuming the deadly puffer fish. Many consumers in the U.S. willingly consume the new low-calorie fat substitute, Olestra, despite packaging labels that declare consumption of the ingredient might cause diarrhea or interfere with nutrient absorption.

These examples demonstrate that different situations and products can result in different perceptions of acceptable risk by consumers. Because federal policy takes into account risk perception, these different attitudes toward safety can affect the development and application of regulatory policy. Biotechnology is an example where public perception of risk varies widely even within a country. The misconceptions often lead to modifications in regulatory policy that are inconsistent with the scientific measurement of risk. Some consumers believe that regulatory policy should strive for "zero risk", not realizing that developing such policy comes at an economic price that might be inconsistent with the degree of risk and might not be necessary to insure public safety. Other potentially costly alternatives, such as identity preservation, are being considered as options for changes in mandatory regulatory policy.

### *Consumer Acceptance of Products of Biotechnology*

Consumers in the U.S., Canada, Europe, Japan and Australia take for granted that the foods they purchase, though with few exceptions don't produce, are safe for themselves and their families and involve very low risk of acute food-borne illness. Consumer concerns are usually reflected in the level of acceptance of a new technology or product. In the U.S. consumer surveys over the last ten years and as recently as February 1999 (International Food Information Council Survey, 1999) have consistently found that between 2/3 and 3/4 of consumers are supportive of biotechnology and they will likely accept the products produced by this technology. The precise level of acceptance will be influenced by the precise nature of the change, however. For example, the movement of a gene from one plant species to another is much more acceptable than transferring a human gene into a plant. In the recent International Food Information Council (IFIC) survey, the majority of consumers in the U.S. were willing to "purchase a food modified by biotechnology to taste better or fresher" (62%) or a food "modified by biotechnology to be protected from insect damage and required fewer pesticides" (77%). The percent of the public willing to accept these products either rose in the case of fresher, tastier food (55%, 1997; 62%, 1999) or remained the same in the case of the insect-protected food (77%, 1997; 77%, 1999). North American consumers rate biotechnology near the bottom of concerns about food safety issues, just below food additive.

### *Factors Affecting Acceptance and Public Policy*

If acceptance is to be considered in the establishment of public policy, it is necessary to understand that the public's view of new technologies is shaped by several factors.

#### *The role of science and technology.*

In the U.S., Canada and Japan (and likely Australia) it is generally accepted that science and technology play a role in improving people's lives. The "heritage" in these countries is to look for different and better ways of doing things and, in general, the public sees science and technology as playing a positive role in effecting this change. Citizens of some European countries seem to have a different attitude toward technological change and are more wary of its long-term consequences.

#### *Physical Separation of GEOs*

Agricultural land in the U.S. is plentiful. The corollary to this situation is that urban dwellers, often unfamiliar with the complexities of agricultural production and wary of new technologies aimed at alleviating these problems, are not juxtaposed next to acres and acres of cropland on which GMOs are growing. For this reason, urban U.S. consumers simply do not think about certain issues relating to GMOs. In Europe, wide open spaces are a rare luxury and a skeptical public often finds themselves located squarely next to fields of GMOs. Such proximity causes consumers to be much more prone to concerns that GMOs might have a negative impact on their shared environment.

#### *Economic Issues*

During this past year, some 80 million acres of genetically engineered crops were grown in the U.S. Only a few thousand acres were grown in the E.U. Therefore a strong economic incentive exists to impose bans against the U.S. Conversely there are compelling economic reasons for the U.S. to resist those bans, since often it is U.S. companies that produce the GMOs and U.S. farmers that grow them. A trade embargo results in a favorable economic cash flow situation for the E.U.

#### *Public Education Efforts.*

In the early 1990's, members of U.S. and Australian public and private research organizations, including universities, began pro-active efforts to educate the public about genetic engineering. The target audience included members of the media and public opinion leaders, both of which play a pivotal role in determining exactly what information people receive regarding an issue, in what way

that information is presented and in what manner this information is used to shape public policy. Trusted governmental and professional agencies became actively involved in information dissemination and education. For example, when recombinant bovine somatotropin (rBST) was introduced, the former U.S. Surgeon General and several other high-level governmental and public-sector agencies, *e.g.* American Medical Association, Food and Drug Administration and American Dietetic Association, released information regarding its safety to the popular press and in peer-reviewed scientific journals. An informational "hot line" was opened to answer questions from the consumer, increasing the openness of the exchange. If this kind of interaction does not occur, an informational void can occur, one which some claim has been quickly filled by Greenpeace in Europe (Hoban 1997).

It is claimed by some that Americans in fact have not been well-educated but are woefully ill-informed about GMOs. This contention, they claim, is supported by the fact that according to the International Food Information Council 1999 poll less than half of those U.S. consumers polled believed that their groceries were free from GMOs, when in fact nearly 60% of the country's processed food contains some GMOs (The Economist, 1999). While this explanation might be true, it is probably equally likely that this "ignorance" results from the fact that U.S. consumers do not care about this aspect of food production and therefore it is not on their "radar screen".

#### *Role of regulatory policy.*

Trust in regulatory authority is also important to consumer acceptance. For many, although certainly not all Americans, hearing that the Food and Drug Administration has approved a food increases their confidence; they don't have the time or resources to do independent research on food safety issues. The attitude of the EU citizenry is quite different, especially in the past few years. European citizens suffered a tremendous decrease in governmental trust during the BSE crisis, acknowledged by many as a classic example of ineffective risk communication (*Nature* 1997). The decisions made during the BSE controversy appeared to many to be based on political expediency rather than on public safety concerns. European governmental agencies are viewed as closely linked to the industries they regulate, a widely held view that has caused a major impediment in establishing trust on food safety issues. U.S. Agriculture Secretary Daniel Glickman emphasized the importance of impartial regulatory agencies in a recent address to the World Agricultural Forum, "We have to make sure that those involved in determining the safety of genetically engineered products are staying at arm's length from the people who stand to profit from them" (Consumer Reports, 1999).

#### *Development of Regulatory Policy*

Genetically engineered rennin, used to make cheese, recombinant BST, used to increase milk output in cattle, and the FlavrSavr tomato, an enhanced fresh market tomato, were the first foods to enter the U.S. market that were developed through genetic engineering methods. Long before these and other products of genetic engineering reached the commercial market, an extensive regulatory network was devised to oversee the experimentation and commercialization of the products. The regulatory network is composed of three major agencies. What are they and what are their roles?

#### *Department of Agriculture (USDA)*

The USDA is entrusted with regulating the transport, growth and propagation of plants through the Animal Plant Health Inspection Service (APHIS). They do not view the products of biotechnology, *i.e.* Genetically Engineered Organisms (GEOs), as fundamentally different from those produced using traditional methods; regulations of GEOs was covered by existing regulations. Despite this view, the USDA soon realized that the assessment of the new products would require in some instances specific information that would lead to some new requirements, *e.g.*, filing extensive

paperwork on the crop itself, the new genetic information introduced into it and the precise manner in which field tests would be conducted. The permit application was reviewed and an environmental assessment issued that outlined the predicted environmental impact of the field test; if no significant impact was expected, the permit issued.

In April 1993, APHIS amended its policy to allow simple notification for six crops, corn, soybean, cotton, tomato, potato, and tobacco, because the largest number of field tests had been done with them and none had wild relatives in the U.S. In 1997 the notification alternative was expanded to include the majority of crops in the U.S., as long as they were not noxious weeds or considered a weed in the area in which they would be released.

Despite the burden of applying for a field permit, the numbers of field releases increased from 8 in 1987 to 1082 in 1998 (see <http://gophisb.biochem.vt.edu/cfdocs/fieldtests1.cfm>). These early burdens did impact the types of crop species tested. Most tested were those with high economic value; the number of traits tested was also limited. The USDA endorsed the shortened process because the early experiences gave them the information they needed to judge possible impacts of a particular gene in a given crop species. This streamlining is beginning to lead to a wider variety of crops and traits being tested.

Organizations can request that an article be removed from the regulatory process, "deregulated" usually late in the commercialization process, following extensive field testing and environmental monitoring. In order for this to happen APHIS issues a "determination" and an environmental assessment. To date 50 petitions for deregulation have been approved by APHIS.

#### *Environmental Protection Agency*

The Environmental Protection Agency (EPA) has jurisdiction over new chemical substances being considered for introduction into the U.S. market. The government has defined all genetically modified microbes, including bacteria, fungi, viruses and protozoa, as new chemical substances, so they come under EPA's authority. This has caused the agency to be involved in the regulation of, for example, bioremediating and nitrogen-fixing microbes. The progress in bringing these organisms to market has been slow.

Several years ago the EPA proposed a new Plant Pesticide Rule, which holds that this agency will regulate and designate all plants engineered with genes for pest resistance as pesticides. The comment phase for this proposed rule ended several years ago, but the final publishing of the ruling has not occurred. This is because large numbers of scientific and professional societies found the policy scientifically indefensible and have openly opposed the rule for several reasons (Council for Agricultural Science and Technology, 1998).

- Pest-resistant plants produced by genetic engineering, may be indistinguishable from conventionally bred plants, but will be regulated differently.
- Regulation should focus on the degree of risk, not on the means by which plants were created
- No scientific evidence shows that a plant's level of resistance to pests (whether a GEO or classically bred) creates hazards in the environment.

If enacted as originally proposed, the ruling would create the dangerous precedent of setting policy based on scientifically flawed principles. Leading members of the concerned scientific societies are meeting with industry leaders to try to fashion a compromise proposal, which will be presented to the EPA for consideration. In the end the agency must balance the scientific facts relating to the subject area with the opinion of the public to whom they are responsible as an agency.

#### *Food and Drug Administration*

The Food and Drug Administration (FDA) has broad authority to regulate the introduction of new foods, whether produced conventionally or through biotechnology. Their policies insure that foods and food products sold in the U.S. are safe for consumers. The agency holds the opinion that the process of producing food is not the important factor in assessing safety; safety should be assessed irrespective of process, meaning that all foods are treated equally in terms of safety assessment.

The FDA is charged with overseeing labeling requirements for foods. This aspect of regulatory policy has been the focus of debate in the U.S. in recent times, heated debate in Europe and Japan. FDA policy guidelines state that foods produced through biotechnology will be subject to the same labeling laws as all other foods and food ingredients, consistent with the agency's philosophy that the process does not dictate the level of regulation. This stance is based on the fact that the information on the label pertains to the composition and attributes of the food, not to the details of the agricultural or manufacturing processes used to produce it.

Labeling will be required for certain foods created by biotechnology, but not simply because they were made using biotechnological procedure. Labeling of the food will be governed by the following:

- No label will be needed if the food or food product is essentially equivalent in safety, composition and nutrition to an existing food.
- Products needing additional safety testing include foods with different nutritional characteristics, those containing genetic material from a known allergenic source (*e.g.* egg, peanut, wheat) or those having elevated levels of antinutritional or toxic compounds.
- Labeling of all other foods will be voluntary.

In 1997 and 1999 U.S. consumer surveys, the vast majority of Americans (78%, 1997; 78%, 1999) either strongly (45%, 1997; 50%, 1999) or somewhat supported (33%, 1997; 28%, 1999) the FDA policy (International Food Information Council, 1997, 1999). Despite this support, labeling for many consumers has become not so much of a food safety issue as it is a personal choice issue; this attitude was reflected in a 1994 survey conducted in Australia (Kelley, J 1994). Some consumers want to know that they are eating something that has been genetically engineered, just out of a right to know. Others want to use the label to identify genetically engineered products so they can use their "economic clout" to vote against the technology. Despite the results reflected in the polls, attitudes toward labeling in the U.S. might be changing. In June 1999, a lobby group opposed to genetic engineering presented a petition, containing 500,000 signatures, demanding the mandatory labeling of GM foods.

Labeling a simple fresh fruit or vegetable requires little extra work on the part of the producer (although it also gives the consumer little extra useful information). In the case of a processed food, however, labeling becomes complicated. A simple bottle of tomato sauce could derive from six different varieties of tomatoes, each engineered with different genes! Enacting a system to monitor such products for accuracy of labeling would indeed be problematic and expensive! Polls indicate that, despite consumer's wishing to vote via the label, most will not be willing to pay the extra costs needed to pay for the "policing" necessary to insure label accuracy (Hoban and Kendall 1993). It has been estimated that setting up a tracking system in the U.S. for the vast quantities of maize and soybeans would likely double the final price of non-GM varieties. This, according to some in the industry, would mean a 25% premium on the final cost of goods. If the addition of the label raises the price of food significantly, it seems that, if the percentage of individuals wanting labels is a minority, these consumers should bear the cost of development of a specialty market of guaranteed,

non-GMO foods. In fact, such a market already exists with organic foods, which the USDA recently declared could not use GMOs.

The differences in attitudes between the U.S. and the E.U. has led to a potential trade war, with the E.U. holding that GMOs are unsafe and refusing to accept them into their markets and the U.S. steadfastly claiming the opposite. At present E.U. regulations prohibit imports of unapproved varieties of genetically engineered corn. This has resulted in U.S. exports to Europe reaching a stalemate, resulting in a potential \$200 million loss for U.S. farmers. The magnitude of the loss is due to the fact that, even though only 5% of the current crop grown for export is from GM varieties, this material has become commingled with non-GMO varieties jeopardizing the entire shipment (Consumer Reports 1999).

In 1998, several FDA Centers met to discuss issues relating to the safety and regulatory status of antibiotic resistance markers (ISB News Reports, 1998). These groups were charged with determining whether and, if so, under what circumstances the FDA should recommend that certain antibiotic resistance genes not be used in crops that end up being used for food and feed. While the transfer of a resistance gene from a plant to a microbe is not viewed as likely to add to existing levels of resistance, nonetheless the FDA proposed that developers of the new foods consider the following:

- Is the antibiotic an important medication?
- Is it frequently used?
- Is it orally administered?
- Is it unique?
- Would there be selective pressure for transformation to take place?
- What is the current level of resistance to the antibiotic in bacterial populations?

If it is determined that the presence of the gene could compromise the use of the particular antibiotic, the marker gene should not be present in the final product. A final ruling on this proposal is expected soon.

#### *Future of Regulatory Policy in the U.S.*

Questions have been raised as to whether "holes" exist in the regulatory structure that would allow certain products to miss adequate scrutiny. For example, the FDA oversees the safety of genetically modified foods, but not any pesticides they express. The EPA regulates the pesticide expressed via genetic engineering, but not the genetically modified food itself. In other words, no agency has formal responsibility for assessing the genetically engineered food *with (sic)* the pesticide in it (The Economist 1999). The existing regulatory structure, however, insures that multiple agencies scrutinize each product and work with the interested industry partner. Inadequate testing of a product in terms of human or environmental safety is certainly not in the best economic interests of the company; an environmental or health safety disaster would be "deadly" for the product and for other products being developed by the company. This is why in the mid-1990's Pioneer Hi-Bred International halted its plans to develop a improved nutrition soybean that contained a Brazil nut protein, found to cause allergies in individuals with Brazil nut allergies.

As more products come to market in the U.S. and as agencies gain more experience in the assessment and regulation of the new products ( *e.g.* risk/benefit analyses), products will move through the system more efficiently. A base of experience will develop that should help the community of regulatory agencies determine when a situation or product requires closer scrutiny. Enactment of regulatory policy must achieve an appropriate blend that reflects a strong commitment to consumer welfare, while allowing industry to move ahead cautiously with new products that have long-term potential benefit for society.

In the U.S. perhaps certain agencies have reached that blend. For example, activist groups complain that the FDA is too lax; industry says it is too strict. It is likely that when both sides find fault, an agency is regulating with an appropriate balance. If regulators are perceived as doing the job mandated by consumers and as stringently controlling industry when appropriate (*e.g. E. coli* 0157:H7 in the U.S.), consumer confidence in the agencies will increase, boding well for the future..

A multitude of products of biotechnology have entered the fields and the marketplace with no examples of unexpected outcomes. Should modification of regulatory policy follow this success? The philosophical basis for FDA policy has allowed them to focus on scientific assessments of risk, while still serving consumers. Encouragement of voluntary labeling is advisable, rather than creating mandated policies of labeling that might later be deemed unnecessary. Within the USDA, the enactment of shortened application processes for transport and field testing has allowed more crops and traits to be tested in the fields. Provided they maintain scrutiny of the scientifically valid problem areas, this strategic change in policy should serve the future of agriculture well. In contrast to the policies of the FDA and USDA, the EPA is currently considering a disturbing change that would focus their regulatory policy on the method by which organisms were developed. This move focuses policy development away from considerations of scientific assessments and, if enacted, sets an extremely dangerous precedent.

#### *Public Acceptance of Genetically Engineered Foods*

The first foods produced through genetic engineering technologies have been looked at very carefully by government agencies, independent health groups and consumers. The scrutiny has been unprecedented in the food sector. In fact hundreds of new foods are introduced into the U.S. market every year from other countries and receive little more than a nod from the federal agencies and no attention by consumers or the media. Once the initial, rather limited offerings of this new technology have been viewed, perhaps the success of a product will not be determined by positive or negative "ad campaigns" but by the desirability of the product to the producer and consumer. To survive in the marketplace, products will need to have tangible benefits to the consumer, *e.g.* enhanced flavor or nutrition, to the processor, *e.g.* easier harvesting and processing, or to the producer, *e.g.* disease resistance or increased yield.

#### **Conclusion**

In the end, consumers must make up their own minds about the acceptability and desirability of genetically engineered foods. If they are satisfied with the *status quo* or do not believe that improvements can be made in the production, environmental impact, nutritional quality or cost/availability of food for themselves or for people worldwide, biotechnology is not likely to be appealing. If they see room for improvement and are willing to support the technologies needed to enact these changes then they should look at the opportunities and decide what criteria should be used to judge these new applications. Making the decision either to use or not to use these technologies has both benefits and risks. Risks should not be judged against the untenable zero-risk paradigm, but against the context of the risks and benefits of current technologies used for agricultural production. Benefits (or perceived benefits) will drive the technology; risks (or perceived risks) will limit its use. Ultimately the users of the technology and the consumers of its products will decide.

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