Review

Plant Biotechnology, 16(1), 73–78 (1999)

Impact of Public Perception on Regulatory Policy for Agricultural Biotechnology

Peggy G. Lemaux

Department of Plant and Microbial Biology, University of California, Berkeley, USA
(Correspondence; Fax, 1-510-642-7356; E-mail, lemauxpg@nature.berkeley.edu)

The new technologies for modifying agricultural crops through genetic engineering hold promise for creating valuable new food and feed sources, which are more affordable and environmentally friendly. With such new technologies come issues relating to the mechanisms by which such products reach the marketplace and how consumer and environmental safety can be assured. Extensive policy and infrastructure have developed in the U.S. for governing the development and release of biotechnological products. These policies have focused on not only addressing consumer and environmental safety issues but also aim to bolster public acceptance by addressing consumer concerns. Much of the unrest relating to the new foods derives from the fact that the majority of the population does not understand how food is grown or processed. Without an historical understanding of how our foods were developed, it is difficult to understand how the foods of tomorrow will be similar to or different from the foods of the past and therefore assessing their safety becomes problematic. The potential for risk in genetically engineered foods can be fairly accurately assessed using current scientific information and this has formed the basis for certain aspects of regulatory policy. However, public concern, 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. For example, compare the adverse consumer reactions to *E. coli* 0157:H7-contaminated hamburger in the U.S. and bovine spongiform encephalopathy (BSE)-tainted beef in the EU to the willing acceptance by many of the risks of picking and eating wild mushrooms and consuming deadly puffer fish. Many consumers in the U.S. also willingly consume the new low-calorie fat substitute despite the warning label, which states that it might cause diarrhea or interfere with nutrient absorption. These examples demonstrate that different situations and products can result in different perceptions of acceptable risk and these different perceptions can affect the development and application of regulatory policy. Biotechnology is an example where public perception of risk varies widely. These misconceptions often lead to modifications in regulatory policy which 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.

1. Introduction

The new technologies for modifying agricultural crops through genetic engineering can result in the creation of new food and feed sources, new sources of products presently made with nonrenewable resources as well as novel products of value to consumers. Historically in the U.S. safety and efficacy of such products have been insured through an efficient and effective regulatory system that both protects the consumer and permits scientific advance. Extensive policy and infrastructure have developed in the U.S. to regulate the development and release of the products of biotechnology. As with any technology, however, there are benefits and risks to its use. There are those who see the value of these approaches as outweighing the risks; others view the risks, however, small, as unacceptable.

At least some of the unrest relating to the new foods derives from the fact that consumers do not understand the technology. It is fair to say that in the U.S. the majority of people do not understand even the basics of how food is grown or processed, let alone the classical genetic procedures by which they are developed. Without such an understanding, it is difficult to grasp how the foods of tomorrow will be produced and how they will be similar to or different from the foods of the past. Therefore assessing their safety can be an issue of concern to consumers because they are fearful of or misunderstand the technologies.

2. Risk assessment—a scientific approach?

The potential for assessing risk in genetically engineered foods can be fairly accurately determined using current scientific information. This has formed the basis for certain aspects of regulatory policy, but public concerns, often inconsistent with the scientific measurement of risk, have also influenced regulatory policy. The basis for this concern depends on the familiarity, "friendliness" and voluntary nature of the risk [1]. For example, com-

pare the adverse consumer reactions in the U.S. to hamburgers contaminated with *E. coli* 0157:H7 or in Europe beef tainted with bovine spongiform encephalopathy (BSE)—situations where consumers were unaware of the risk—to the willing acceptance by many of picking and eating wild mushrooms or eating improperly prepared puffer fish.

These examples demonstrate that different situations and products can result in different perceptions of acceptable risk by consumers and these different perceptions can affect the development and application of regulatory policy. Biotechnology is an example where the public perception of risk varies widely within a national population and among countries. The differing perceptions and misconceptions can often lead to modifications in regulatory policy, which are inconsistent with the scientific measurement of risk. Some consumers believe that regulatory policy should strive for "zero risk", not realizing that developing policies consistent with this philosophy comes at an economic cost that might be inconsistent with the degree of risk and might not be necessary to insure public safety.

3. 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.

4. 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.

5. 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.

5.1 The role of science and technology

In Japan and the U.S. it is generally accepted that science and technology play a role in improving people's lives. In the U.S. and Japan, the "heritage" is commonly to look for different and better ways of doing things and, in general, the American and Japanese populations have a positive view toward the role of science and technology 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.

5.2 Involvement in 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, who play a pivotal role in determining exactly what information people hear and read regarding an issue, in what way that information is presented and in what manner this information is used to shape public policy. If scientists and food professionals are reluctant or chose not to make themselves available to reporters and public officials or are not prepared to talk to them in an effective manner, media coverage and public policy can be skewed. Writers and public officials tend to be more educated when scientists are willing to share their views.

Trusted governmental and professional agencies need to be actively involved in information dissemination and education. For example, when recombinant bovine somatotropin (rBST) was introduced, the highly respected, former U.S. Surgeon General C. Everett Koop issued a statement that milk from rBST-injected cows was safe. In addition, several other governmental and public-sector agencies, e.g. American Medical Association, Food and Drug Administration and American Dietetic Association, released information in the popular press, peer-reviewed scientific journals as well as making a "hot line" available to answer questions on the safety of the product, thereby increasing the openness of information exchange (Christine Bruhn, personal communication). If this kind of engagement does not occur, an informational void can occur. It is the opinion of many that this occurred in Eu-

rope and the void was quickly filled by Green Peace [2]. In a scientifically conducted survey of Japanese consumers in 1998, it was noted that they continue to trust independent, scientific experts with strong support for the Japanese Information Center, but support for the Ministry of Agriculture, Forestry and Fisheries and Ministry of Health and Welfare is declining (Thomas Hoban, personal communication)

5.3 Role of regulatory policy

Trust in a 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 to do independent investigations of food safety. The situation in Europe is quite different, especially in recent times. European citizens suffered a tremendous decrease in governmental trust during the BSE crisis, acknowledged by many as a classic example of ineffective risk communication [3]. 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 view which, if widely held, will be a major impediment in dealing with future food safety issues.

6. 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 by genetic engineering. Long before these and other products of genetic engineering reached commercialization, there was an extensive regulatory network devised to oversee experimentation and commercialization of the products. What are these agencies and what are their roles?

7. United States Department of Agriculture

The USDA is entrusted with regulating the transport, growth and propagation of plants through the Animal Plant Health Inspection Service (APHIS). The policy of this agency states that they do not view the products of biotechnology, Genetically Engineered Organisms (GEOs), as fundamentally different from those produced using traditional methods. Regulations of GEOs is covered by existing regulations, which were implemented for other technologies. The USDA realized, however, that the assessment of the products of the new technology in some instances would require specific information that would lead to the introduction of some new requirements. This included the filing of extensive paperwork that provided great detail about the crop, the new genetic information introduced into it and, in the case of field testing, the precise manner in which the test would be conducted. The agency then reviewed the permit application and issued an environmental assessment, which outlined the environmental impact of the field test. If no significant impact was observed, the permit was issued. This process was time-consuming to complete and often required months for the permit to issue. The paperwork was burdensome and deterred many public sector scientists from pursuing field testing. In April of 1993, APHIS amended its policy to allow a notification alternative for the introduction of transgenic plants from six crops, corn, soybean, cotton, tomato, potato, and tobacco, provided the release was done in accordance with policy. These six plants were chosen 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 amended to allow the alternative notification procedure to be used for 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. In addition, certain plant virus sequences previously regulated were made exempt because it was deemed that they did not pose a significant risk of creating a new virus. Certain other changes were enacted to ease the reporting burden.

Despite the burdensome nature of the permit process for field testing of transgenic plants, the numbers of field releases increased steadily, from 8 in 1987 to 1,105 in 1998 (**Fig. 1**). However, these early burdens likely skewed testing to certain economically important crops and limited the number of traits that were examined. This undue burden precluded certain experimentation that was needed to assess questions of environmental risk and consumer safety, creating in some minds, a regulatory dilemma. The shortened process has drastically reduced the time required to obtain a permit. The USDA felt comfortable with this shortened process because their earlier experiences gave them better predictive value with which to judge the possible impacts of a particular gene on a given crop species. This streamlining is beginning to lead to a wider variety of crops and traits being tested (**Fig. 2**).

Organizations can request that an article be removed from the regulatory process, usually late in the stages of commercialization following extensive field testing and environmental monitoring. In order for this to happen APHIS issues a "determination" and an environmental assessment. To date 20 such determinations have been issued.

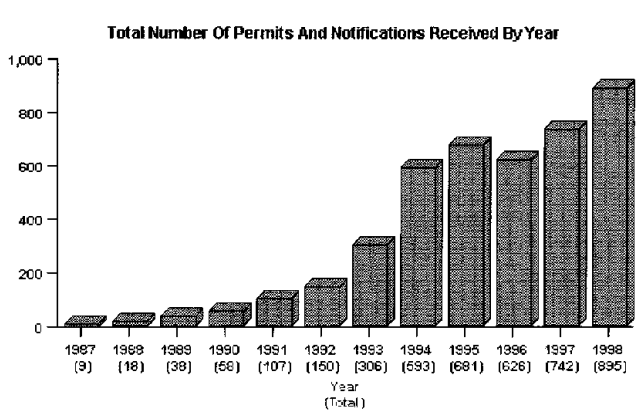

Fig. 1 Increase in field releases from 1987 through 1998.

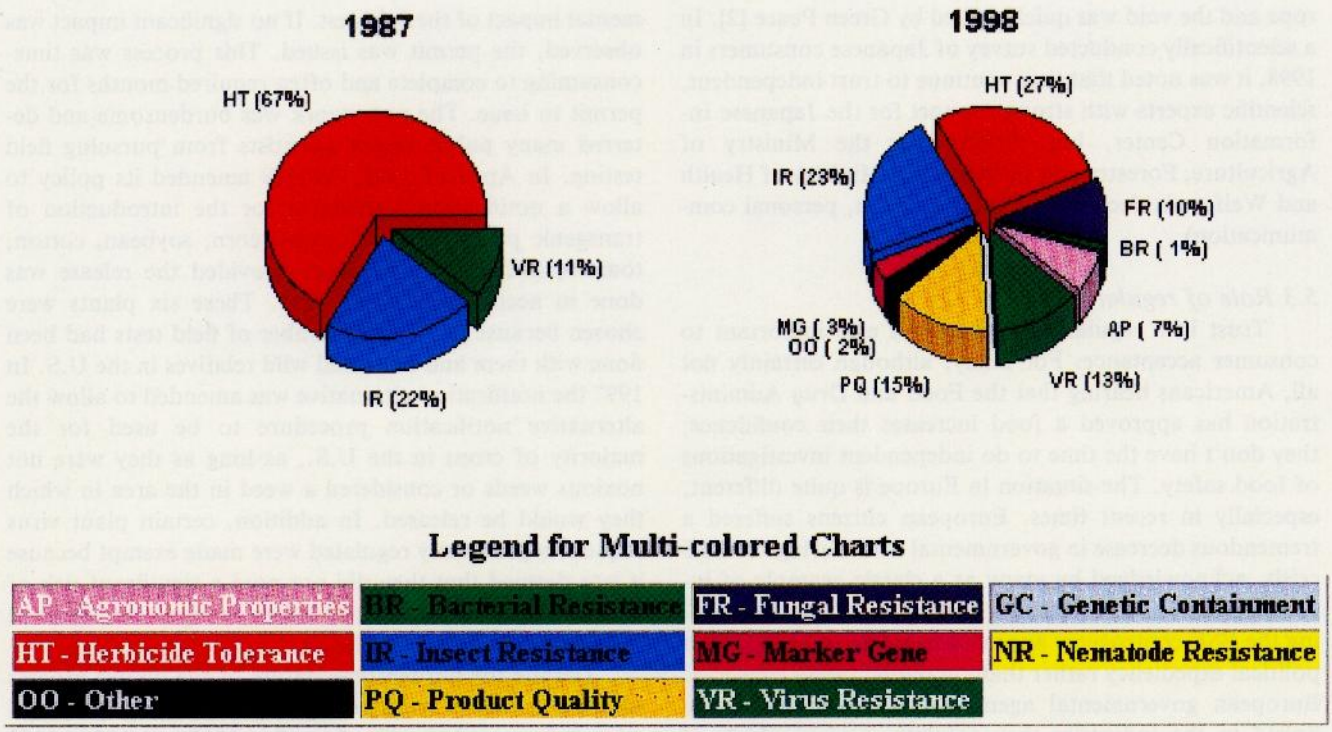

Fig. 2 Pie chart of phenotypic traits of transgenic plants in 1987 compared to 1998.

8. United States 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 this 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.

Recently the EPA has 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. Large numbers of scientific and professional societies have found the policy scientifically indefensible and have openly opposed the proposed rule for several reasons [4].

(1) Pest-resistant plants produced by genetic engineering may be indistinguishable from conventionally bred plants, but will be regulated differently.

(2) Regulation should focus on the degree of risk, not on the means by which plants were created.

(3) No scientific evidence shows that a plant's level of resistance to pests (whether a GEO or classically bred) creates hazards in the environment.

The comment phase for this law ended years ago but the final publishing of the proposal has not occurred because the scientific community has become involved and spoken out against the ruling based on scientific inconsistencies. Industry leaders are presently meeting with the leading members of the scientific societies in order to fashion a compromise proposal, which will be presented to the EPA for consideration. In the end the agency must balance the scientific facts with the opinion of the public to whom they are responsible as an agency. If enacted as it was originally proposed, it creates the dangerous precedent of setting policy based on scientifically flawed principles.

9. United States Food and Drug Administration

The U.S. 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.

10. Labeling issues

The FDA is charged with overseeing labeling requirements for foods. As this relates to products of biotechnology, there has been much debate over the labeling issue in the U.S., but more prevalently abroad. Relevant to this issue is a survey, conducted in Australia [5], which showed that labeling was primarily an issue of personal choice. So some consumers want to know that they are eating something that has been genetically engineered, not so much for food safety concerns but just out of a right to know. Despite this rather strong preference, the reality is that invariably consumers will answer "yes" if asked whether they want more information, even if they do not use that information to make a decision.

More importantly, perhaps, they are not willing to pay for the added information [6].

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. These sentiments are embodied in their policies.

(1) Labeling will be required for certain foods created by biotechnology, but not simply because they were made using biotechnological procedures.

(2) No label will be needed if the food or food product is essentially equivalent in safety, composition and nutrition.

(3) Products that will be captured for additional safety testing will include those 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.

(4) Labeling of all other foods will be voluntary.

In a 1997 U.S. survey 78 percent of American consumers supported this policy [7]. The same approach to labeling has been enacted in Japan. In stark contrast is the situation in Europe where labeling practices have varied dramatically from one country to the other, from full disclosure of any ingredient from a GEO (Denmark) to no labels being required for substantially equivalent foods (United Kingdom). Harmonization of this policy is necessary for the EU to allow movement of foods within the member states.

In the past few months several of FDA's Centers met to discuss issues relating to the safety and regulatory status of antibiotic resistance markers [8]. These groups were charged with determining whether and, if so, under what circumstances the FDA should recommend that a certain antibiotic resistance gene 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 proposes that developers of the new foods consider the following:

1. Is the antibiotic an important medication?
2. Is it frequently used?
3. Is it orally administered?
4. Is it unique?
5. Would there be selective pressure for transformation to take place?
6. 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.

Comments on this proposed regulation are being sought until December 7, 1998 after which the FDA will consider the comments, revise the draft and publish it as an official government document.

11. Variation in regulatory timelines

Because of variations in the regulatory structures in the various countries, there is wide variation in the timelines for genetically engineered products to reach the field and the marketplace (Ariane Konig, personal communication). The number of products evaluated in the U.S. (34 products) is nearly six times that in the EU (6 products). In addition the average time required to evaluate products in the EU (18–19 months) is three times longer than that in the U.S. (6 months). The acreage involved in field testing was also higher in the U.S. (30 million acres) than in the EU (20,000 acres).

12. Future of regulatory policies in the U.S.

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 regulatory agencies determine when a situation or product requires close scrutiny.

Regulatory agencies need to achieve an appropriate blend in their regulatory policy that shows a strong commitment to consumer welfare, while allowing the industry to move ahead with new technologies 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 are 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? If so, has modification of existing policies occurred?

The philosophical basis for FDA policy has allowed them to focus on scientific assessments of risk, while still serving consumers. Encouragement of voluntary labeling of early products was probably advisable, rather than creating mandated policies of labeling that might not be later deemed necessary. 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 standing policies of the FDA and the recent relaxation of policy at the USDA, the EPA is currently considering a disturbing change in policy that

would focus their regulatory policy on whether organisms were developed by classical or molecular methods. This move focuses policy development away from considerations of scientific assessments and, if enacted, sets an extremely dangerous precedent.

13. Harmonization of worldwide regulatory policy and the future of biotechnology

Once the initial offerings of biotechnology have been scrutinized by regulatory agencies and the public at large, the critical factors influencing product success in the U.S. will likely not be positive or negative press coverage but the safety and desirability of the product to the producer and consumer. To survive in the marketplace, products will need to have tangible benefits to the producer, e.g. disease resistance or increased yield, to the processor, e.g. more easily harvested or processed foods or to the consumer, e.g. enhanced flavor or nutrition. Educational efforts must focus on articulating the potential environmental and health safety benefits of these technologies, if indeed they are realized.

At present different regulatory systems exist in different countries of the world. Variations exist among the major world markets in the submission procedures and labeling requirements and there is no mutual recognition amongst the nations of each other's policies. In the global marketplace it will be necessary to develop regulatory frameworks that are harmonized and lead to a transparent exchange of food and feed worldwide. Adoption of policies that are based on minimizing (but not eliminating) risk, while allowing the new technologies to improve agricultural production, environmental quality and consumer safety, should be adopted. When this can be achieved, the rightful place of biotechnology as a tool, albeit not a solution, for agricultural improvement can be realized.

References

[1] Meyers, J.M., Craigmill, A.L., 1994. California Agriculture **48**: 8–9.

[2] Hoban, T.J., 1997. Nature Biotech. **15**: 232–234.

[3] Nature, 1997. **385**: 8.

[4] Council for Agricultural Science and Technology, 1998. The Proposed EPA Plant Pesticide Rule. October 1998, Issue 10.

[5] Kelley, J., 1994. Public Perceptions of Genetic Engineering: Australia: 1994, Australian National University, Department of Industry, Science and Technology.

[6] Hoban, T.J. and Kendall, P.A., 1993. Consumer Attitudes about Food Biotechnology. Raleigh, North Carolina: North Carolina Cooperative Extension Service.

[7] International Food Information Council (IFIC), 1997. News release on consumer survey conducted by the Wirthlin Group.

[8] Information Systems for Biotechnology News Reports, 1998. FDA Addresses Use of Antibiotic Resistance Marker Genes. October 1998, 1–2.