

**A Consumer Perspective on Regulating Agricultural Biotechnology.  
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Thank you very much for the opportunity to participate in this important meeting. Agricultural Biotechnology is a topic surrounded by great controversy world-wide. I hope that the discussions at this meeting will lead to constructive ideas on how to resolve some of that technology's most pressing issues.

This paper consists of three separate sections. First, for those of you unfamiliar with the organization I work for, this paper describes the Center for Science in the Public Interest ("CSPI"), outlines its Biotechnology Project, and gives an example of what CSPI is advocating to strengthen U.S. regulation of agricultural biotechnology products. Second, the paper identifies issues that need to be explored by nations setting up regulatory systems for agricultural biotechnology. Third, the paper discusses what are the essential requirements for a regulatory system if one of the goals is for consumers to trust the regulatory process and to have confidence in safe products that go through that process. Without trust in the regulatory process, it is impossible for consumers to have confidence in and support for agricultural biotechnology products that are found safe after governmental review.

I. The Center for Science in the Public Interest and its Biotechnology Project

CSPI is a nonprofit consumer-advocacy organization that focuses on improving the safety and nutritional quality of our food supply and on reducing the damage caused by alcoholic beverages. CSPI seeks to promote health through educating the public about nutrition and alcohol; it represents citizens' interests before legislative, regulatory, and judicial bodies; and it works to ensure that advances in science are used for the public good. CSPI primarily focuses its activities in the United States, although it does have a satellite office in Canada. CSPI is also involved in international activities involving food safety and labeling issues, such as the Codex Alimentarius and the Trans-Atlantic Consumer Dialogue.

CSPI is primarily supported by the 800,000 member-subscribers to its *Nutrition Action Healthletter*. CSPI receives no funding from industry or the federal government. CSPI does receive some funding from independent philanthropic foundations. In fact, CSPI's Biotechnology Project is partially funded by the Rockefeller Foundation.

A. CSPI's Biotechnology Project

Approximately 18 months ago, CSPI began an advocacy project on agricultural biotechnology. Some of that project's goals are to accurately identify the risks and benefits of biotechnology, to ensure that the U.S. regulatory system is up to the task of preventing significant risk, and to keep the public informed about the facts surrounding agricultural biotechnology.

The project was started partly because the debate surrounding agricultural biotechnology was becoming dominated by certain proponents and opponents of the technology who did not always provide scientific support for their positions on the technology's benefits and risks. CSPI, on the other hand, advocates policies and positions based on an objective assessment of all the current facts and evidence available, even if the resulting positions are not politically correct for a liberal consumer organization. Thus, CSPI's biotechnology positions are based upon the current evidence about the risks and benefits of biotechnology, not an ideological viewpoint that agricultural biotechnology is inherently good or bad.

The positions that CSPI's Biotechnology Project have taken since its inception have been somewhat controversial in the United States. For example, CSPI recently stated that, based on its review of currently available evidence, "the genetically engineered foods that are currently on the market are safe" to eat and that environmental risks associated with those crops are manageable. (CSPI 2001a). Although other consumer groups agree with that conclusion, they have not actively voiced that position. (Consumer Report 1999; Nemecek 2001). Also, CSPI has stated on numerous occasions that currently engineered crops are yielding benefits to farmers and the environment by reducing the use of pesticides and increasing yields. (Jaffe 2001a; Jacobson 2001a; Jacobson 2001b; CSPI 2001). For example, according to the National Center for Food and Agriculture Policy, Bt cotton has enabled farmers to cut their insecticide use by millions of pounds and increased their net revenue by millions of dollars. (Carpenter and Gianessi 2001). That is a benefit to farmers, the environment, and presumably non-target species that are normally killed by the toxic pesticides sprayed in cotton fields. Similarly, farmers who use herbicide-tolerant soybeans spray their crops less often and use glyphosate herbicides that appear to be safer than some of the herbicides they have replaced. The herbicide-tolerant crops also encourage no-till farming which should reduce soil erosion and decrease water pollution. CSPI publicly acknowledges these beneficial applications and wants to ensure that these benefits continue to be realized in the future. CSPI has been disappointed that other crops that could provide similar environmental benefits, such as Monsanto's Bt potato, have not been planted by farmers due to fear of a consumer backlash and a loss of market for that crop.

Although current biotech crops have provided benefits to farmers and the environment, they have not benefitted consumers who eat foods derived from those crops. Current biotech crops have not lowered food costs nor have they provided beneficial nutritional qualities or enhanced taste. Hopefully, future generations of biotech crops will provide some consumer benefits. For many consumers in developed countries, without direct benefits, there is no reason to take even the smallest of food safety risks to eat biotech foods.

Of course, CSPI acknowledges that agricultural biotechnology has real risks that need to be assessed and addressed before products are marketed. From the consumer's point of view, the key question about biotech foods is "Are they safe?" Thus, before a biotech food is marketed, there needs to be a determination that the engineered protein is not an allergen, that there is no toxic effect from the engineered crop, and that there is no other unintended effect from the genetic transformation. (CSPI 2001a; NRC 2000). There are also possible environmental risks from engineered crops. For example, there is the potential for harm to non-target species, or the spread of the introduced gene and its characteristics to wild relatives, or the development of pesticide resistance in insects or weeds. (CSPI 2001a; NRC 2000). Each possible environmental consequence needs to be thoroughly evaluated and adequately addressed before any biotech crop is released into the environment.

B. Mandatory Pre-Market Approval of GE Foods is Needed to Strengthen the U.S. Regulatory Structure

Many American consumers have concerns about eating biotech foods. (CSPI 2001b; Foreman 2001). CSPI's Biotechnology Project hopes to restore public confidence in safe and beneficial products of agricultural biotechnology by advocating a strong, but not stifling, regulatory structure for those products. For example, CSPI advocates that the U.S. Food and Drug Administration ("FDA") should make an independent determination that each biotech food is safe for human consumption before it can be marketed. A mandatory pre-market approval system would increase public trust in the governmental review of those products and public confidence in the safety of biotech foods. That process also would increase the likelihood that consumers would accept biotech foods, allowing farmers and the environment to realize the benefits which the biotech crops were designed to provide.

1. FDA's Current Policy Toward Biotech Crops

Currently, FDA does *not* formally approve any GE crops as safe to eat. (FDA 1992; Foreman 2001). FDA has the authority to approve new food additives, but says that the GE plants developed so far do not fall within that authority. Instead, FDA adopted a voluntary process to review safety data provided by seed companies to ensure compliance with existing laws. That consultation process, which FDA states is "not a comprehensive scientific review of the data generated by the developer," (FDA 1997) culminates with FDA stating that it has "no further questions . . . at this time" regarding the food. (FDA 1999). Although no human health problems with GE crops have been detected and every US developer has voluntarily consulted with FDA, this industry-driven process is not the most effective way to protect human health and engender public confidence. As the next generation of biotech crops are marketed in the coming years, the scientific safety issues raised by more complex biotech crops (such as nutritionally enhanced crops or plants engineered with new metabolic pathways) cannot be adequately assessed with this industry-driven voluntary consultation process.

Recently, FDA proposed regulations that would mandate notification before a GE plant intended for food or feed is marketed. (FDA 2001). Although that proposal improves upon the current process by mandating agency review and increasing transparency, it does not change the agency's scientific review nor will it result in an official safety determination. (Jaffe 2001b). After the mandatory notification, FDA still does not respond with an affirmation that the food is safe to eat. Also, if a developer markets a biotech food without notifying FDA, FDA still must prove the food is adulterated before it can be removed from commerce.

2. A Proposal for a Mandatory Approval Process

FDA should establish a new mandatory approval process, unrelated to the current food additive process, for GE crops. FDA should promulgate regulations that establish testing and data requirements based on advice from a National Academy of Sciences panel of scientists charged with determining what scientific information is needed to assess food-safety concerns of such crops. In addition, the mandatory approval process should ban any biotech food with a new allergen as well as prohibit approvals for crops intended for animal feed but not human consumption. If new legislation is needed so that FDA can implement an approval process, Congress should pass such legislation.

A mandatory pre-market approval process at FDA for biotech foods would have numerous advantages over the current system. First, an approval by FDA provides an independent check on industry's determination of safety and requires FDA to share responsibility for that safety determination. Second, it eliminates the gap in the U.S. regulatory system which allows some biotech foods but not others from being marketed without pre-approval. Currently transgenic animals require pre-market approval by FDA (Matheson 1999; Lewis 2001) and pesticidal plants require pre-market approval by EPA (EPA 2001), yet non-pesticidal transgenic plants only need go through the FDA's voluntary consultation process. Third, an approval process would not be more burdensome to applicants than the current voluntary process since the industry states that it already conducts all reasonable tests to ensure the food-safety of its products. Finally, seeking approval from FDA before marketing the biotech crops would treat Americans the same as Europeans and Canadians, both of whom only eat biotech crops after they have been affirmatively approved safe by their respective governments. (MacKenzie 2001).

## II. Establishing Laws and Regulations Governing Agricultural Biotechnology

Currently, developed and developing countries are exploring legal authorities and procedures to regulate agricultural biotechnology. In almost all cases, the goal of those laws and regulations is to protect human health and the environment. If a successful system is put in place, human health will be protected because only products that are safe to eat will be marketed. Similarly, the environment will be protected if the environmental risks for each GE organism are properly analyzed before that organism is released into the environment and those risks are either eliminated or effectively managed prior to release. Then consumers will trust the government regulatory process, have confidence in the resulting safety determinations, and embrace those safe products.

### A. Characteristics of an Ideal Regulatory System

There are certain characteristics of an ideal regulatory system for agricultural biotechnology. They are as follows:

- **Adequate Authority.** There must be sufficient legal authority to subject the products to both a thorough food-safety and environmental approval process. The regulatory system must capture all products one is concerned about, prevent marketing of any products without approval, and provide enforcement authority for any problems that might arise. The regulatory system should also address not just commercial products but all stages of development of a product from laboratory research to commercial production.
- **Flexibility and Adaptability.** In an area where science, technology, and commercial products change rapidly, the regulatory system needs flexibility to adapt to new technologies, new evidence on risks, and new types of products. The regulatory system also should be able to learn from its experiences regulating products and adapt accordingly. Of course, the more flexible and adaptable the system, the less certainty there is in that system for both the users (technology developers) of the system and the observers (stakeholders). Thus, the ideal regulatory system is able to adapt as scientific knowledge and experience dictates yet remain within a framework that gives users and observers some degree of certainty about the regulatory process.

- **Equitable and Fair.** The regulatory process should be equitable and fair in several ways. First, it should treat similar products in a similar manner. Second, it should review products using established criteria and standards. It is important that the users and observers of the regulatory system know what criteria and standards the products will be judged against and who will be doing the assessments. Finally, an equitable and fair system will allocate resources based on relative risks, so that products with a greater chance of food-safety or environmental risk receive more scrutiny than products with less risk.
- **Easily Understandable Process.** A good regulatory system is one that is easily understandable to all persons involved as well as outside observers. There should be a clear roadmap of the process and guidance on what is expected of an applicant. The process must be clear to stakeholders and the public, especially if one wants to instill public trust in the system. As stated by the U.S. National Research Council: “The credibility of the regulatory process and acceptance of products of biotechnology depends heavily on the public’s ability to understand the process and the key scientific principles on which it is based.” (NRC 2000).

## B. New Versus Existing Law

A threshold question that must be addressed when regulating agricultural biotechnology is whether to use existing laws or establish a new law. The United States is an example of a country that decided to use existing laws to regulate products of agricultural biotechnology. (OSTP 1986). The advantages of using existing laws are that the regulatory structure is quicker to implement and established agencies and practices are already in place. A disadvantage of using existing laws is that those laws usually are not specific to biotechnology and may require convoluted legal reasoning in order to apply to biotechnology products. Also, adapting existing law to agricultural biotechnology may involve multiple laws and agencies, resulting in a complex and not easily understandable process. If a country uses existing laws, there is also a concern that some products may be under- or over-regulated (based on their relative risk) while other products may fall through the cracks and avoid regulation altogether.

In the United States, the use of existing laws has led to a complex patchwork of laws and agencies regulating biotech products under different standards and procedures. (Jaffe 1987; OSTP 1986). That system does not approach the ideal regulatory system because it is not easy to understand, lacks adequate authority to capture all potentially dangerous products, and does not treat all products in a fair and equitable manner.

Other countries, such the European Union and its member countries, have established new laws and/or regulations to specifically address agricultural biotechnology products. (Mackenzie 2001). The advantage of these new laws is that they are tailored specifically to that technology and address any special issues in regulating that technology (such as increased public participation and transparency due to the public debate surrounding biotechnology). One disadvantage of establishing a new law is that it takes a long time to enact laws and moratoriums may be required until the law has been passed and regulations put in place. Also, enacting new laws may require the government to perpetually play catch-up, since technological change moves quicker than legal or governmental institutions. In addition, it may be overkill to establish a new law for each new technology. (McLean et al. 2002).

### C. Other Key Issues for any Regulatory System

There are at least two other key issues that must be addressed for any regulatory system for agricultural biotechnology. The first issue is what scope of products will be covered in the regulatory process. Does the system capture products based on the process or method of production of the product or the characteristics of the final product? Does the regulatory process cover all recombinant DNA products or only products that could not be achieved with conventional breeding? Those questions and many others need to be answered in defining the scope of products to be regulated. In addition, any definition needs to look years into the future to address scientific and technological changes that might occur which should be captured by the regulatory system.

The second issue is what safety standard should be used for approving the biotech products. Should the developer need to prove a “reasonable certainty of no harm?” Should the safety standard address the harm as it relates to the average person or to a highly sensitive individual (such as a child or an elderly person)? Should the standard be whether the biotech food is “substantially equivalent” to its conventional counterpart? Should only risks, or both risks and benefits be involved in approving the product? Should the standard be the same or different for food-safety and environmental issues? Those questions and many others must be analyzed to decide on safety standards for the regulatory system for agricultural biotechnology.

### III. How to Achieve Consumer Trust in the Agricultural Biotechnology Regulatory Process

At this conference, there has been much discussion about the need to achieve consumer confidence in the products of biotechnology. This section of my presentation sets forth what needs to occur within the regulatory process to achieve both consumer trust in that process and consumer confidence in the products that emerge out of that process with a safety determination.

#### A. Mandatory Pre-Market Approval With Established Safety Standards

To achieve consumer trust in the regulatory process, that process must be a mandatory approval process by a government agency that is accountable to the public. There must be adequate authority so that all products need approval and any products not approved are illegal if marketed. A voluntary process, such as the FDA voluntary consultation process for transgenic crops described earlier in this paper, does not meet this criteria. Similarly, Japan’s system of ensuring the safety of biotech foods with a series of voluntary guidelines is inadequate (although Japan is moving to make that system mandatory). (MacKenzie 2001).

A mandatory pre-market approval system should set a minimum food-safety standard that must be met for all biotech foods. That food-safety standard should be met by each product before any benefits analysis or other societal considerations are analyzed in determining whether the product should be approved for the marketplace. Consumers will not trust a system in which products are approved with unacceptable food-safety risks because the benefits outweigh those risks. Similarly, for consumers to trust a regulatory process, the decisions made by the government agency must be based on a scientific risk-based analysis. (Cohen 2001). That analysis must follow specific established criteria that limit the agency’s discretion on the factors it can use to base its decision.

It is not inappropriate for a regulatory system to require a benefit or market analysis as

part of the approval process but those factors should not allow an otherwise unsafe product to be marketed. For example, the approval process in Argentina requires a market analysis as part of the approval process. (Burachik and Traynor 2001). It might be appropriate to deny an application for a product that met the safety standard because the market analysis showed that it would hurt trade relations with important trading partners. It would not be appropriate, however, to approve a product that did not meet the food-safety standard but would have great benefits to the society because it would significantly increase export markets.

#### B. A Transparent Regulatory Process

An important characteristic for the regulatory process is transparency. A transparent system will provide complete access to the following information:

- Access to information about the regulatory process, including who is involved in the process, what are their responsibilities, and how they will carry them out;
- Access to the applications received by the agency as well as supplements to the application and any documents produced by the agency regarding the application's completeness; and
- Access to a clearly written decision document that provides the basis for the agency's determination. (McLean et al. 2001).

In addition, in a transparent system, the agency should publicize that products are being reviewed by announcing when applications are received, and when and where those applications can be reviewed by the public.

Although a transparent regulatory system strives for complete public access to all information provided by the applicant, that system should allow restricted access to genuine confidential business information ("CBI"). To limit that exception to information that is truly confidential, the regulatory agency should require up-front justifications for CBI and then make quick decisions on the validity of any claims. In addition, certain information essential to the public, such as information from safety testing, should not be allowed to be claimed as confidential. An ideal regulatory system should avoid the situation in the United States' Department of Agriculture where the extent of CBI submitted to the agency "hampers external review and transparency of the decision-making process." (NRC 2002).

#### C. Public Participation in the Regulatory Process

Public participation in the regulatory process is essential for consumer trust in that process. Public participation should take several different forms, including the opportunity to provide information and comment on regulations, guidance, and product applications as well as the opportunity to provide oral and/or written testimony at public hearings. (McLean et al. 2002.)

Governmental agencies should make a special effort to solicit information from stakeholders to ensure that all points of view are heard before regulatory decisions are made. For example, the USDA has recently been criticized by the National Research Council ("NRC") for its inability to involve the public in policy development and decision making on agricultural biotechnology issues. NRC recommended that USDA specifically solicit public input for product-specific determinations as well as precedent-setting decisions. (NRC 2002).

Public participation is also a useful method for government agencies to obtain expert

scientific advice. Many different regulatory systems for agricultural biotechnology make use of outside scientific experts on science advisory committees to supplement in-house scientific expertise when novel scientific questions arise. The scientific expertise that those committees provide to the government is extremely helpful, but it is very important that those committees only provide advice. They should not make regulatory decisions on behalf of the government. For example, in Argentina and Egypt, “the national biosafety committees are empowered to deny a request or to hold it pending receipt of additional information from the applicant.” (Cohen 2001; Burachik and Traynor 2001; Madkour et al. 2000). The experts on those committees are not government employees accountable to the public. They should provide scientific advice on the merits of an application, not be empowered to decide whether to approve or deny that application.

In many instances, the membership of advisory committees include scientists with a conflict of interest because they conduct biotechnology research or have a financial interest in the specific products being reviewed. For example, Argentina’s biosafety advisory committee includes many members who conduct research at public institutions, work collaboratively with biotechnology companies, or belong to industry organizations, all of whom have at least the potential for a conflict of interest. (Cohen 2001; Burachik and Traynor 2001). To avoid possible conflicts of interest and to ensure that independent decisions are made by institutions directly accountable to the public, scientific advisory committees should not allow participation by experts with conflicts of interest.

#### D. The Importance of Independent Government Decisions

It is important that decisions approving biotech foods are made by independent government agencies, preferably agencies whose sole responsibility is to ensure either safe food or a safe environment. A decision by an agency whose sole function is to ensure safe products is more trustworthy to the public than a regulatory decision by an agency whose primary role is to promote agricultural interests.

When deciding which agency should regulate agricultural biotechnology, it is important to avoid agency conflicts of interest. For example, in the United States, the Department of Agriculture’s primary responsibility is to promote agricultural interests and issues in the United States and abroad. They also perform some regulatory functions, including the regulation of releases of genetically engineered organisms into the environment. Those dual roles, of a promoter and also a regulator, can conflict with each other and may result in a less than completely rigorous regulatory process. (Jaffe 1987). In the case of USDA, its regulatory process and the application of that process has not been as rigorous as many would want, possibly because of this inherent conflict between the agency’s mandate and goals. Other countries, such as Egypt and Argentina, have followed the U.S. model and have also established the Ministry of Agriculture as the entity overseeing environmental issues surrounding agricultural biotechnology. (Cohen 2001). Therefore, to achieve consumer trust in the regulatory process, it is imperative that the agency regulating agricultural biotechnology have a clear mandate that its primary responsibility is to protect the public health or the environment.

#### E. Post-Approval Monitoring and Enforcement

In order for consumers to trust the regulatory process for agricultural biotechnology, that process must conduct post-approval activities. There should be post-approval monitoring for

adverse environmental or health effects. Although one would assume that post-approval monitoring is an obvious part of a regulatory system, many current biotechnology regulatory systems don't carry out those activities in a consistent manner. (McLean et al. 2002). For example, in the United States, the EPA ensures that there is post-approval monitoring for pesticidal plants. At USDA, however, when a biotech crop is commercialized, it applies for a determination that it is no longer a plant pest and seeks to be deregulated (i.e. a status where the crop is no longer regulated by USDA). If this occurs, as has been the case with glyphosate tolerant soybeans and numerous other crops, USDA no longer has any legal authority over those crops and no environmental monitoring can be required. (NRC 2002).

The other post-approval activity that is essential to consumer trust is enforcement. The regulating agency needs adequate authority to carry out enforcement actions, such as conducting inspections, sampling food products, recalling unsafe products, and limiting environmental problems that arise. Adequate authority alone is not sufficient, however, unless the regulatory agency has adequate resources to carry out enforcement activities, since inspections, laboratory testing, and legal actions require significant financial and personnel resources.

In the United States, enforcement by agencies regulating agricultural biotechnology has been minimal or nonexistent and this has played a significant role in the public's distrust of the technology. Although USDA has conducted infrequent inspections of field trials for approved releases and addressed some noncompliance through enforcement mechanisms, EPA does not conduct similar inspections, instead relying upon self-monitoring by the developers of biotech crops. (OSTP 2001). That EPA policy contributed to the problems with StarLink corn. EPA approved StarLink corn with numerous restrictions on its use, but did not conduct any inspections or testing to ensure that Aventis (the developer of StarLink), the farmers growing the StarLink corn, or the other parties in the grain handling system were abiding by those restricted conditions. If EPA had conducted inspections and testing, the United States might have avoided the extensive StarLink corn contamination in the food supply. EPA policy's of not inspecting to ensure that registration requirements are being implemented may also speed up insect resistance to Bt crops. For example, in EPA's registration of Bt corn products, the agency has required that farmers growing Bt corn plant refuges of non-Bt corn to prevent insect resistance from developing. In the past two years, the industry estimates that 20-30% of all Bt corn farmers have not complied with the Bt corn refuge requirements, yet no enforcement activities have taken place to rectify that noncompliance. There is nothing worse to shatter the confidence of the public in a regulatory system than for that system to approve products with certain restrictions but conduct no activities to see that the restrictions are being met.

There are some countries where inspections and enforcement does occur regularly. In Argentina, all field releases are monitored by inspectors and inspected at least once. (Burachik and Traynor 2001). In Egypt, the government assigns qualified inspectors to ensure adherence to any biosafety requirements. (Madkour et al. 2000). Similarly, in South Africa, inspectors investigate to ensure that field trials are carried out in accordance with applicable laws and permits. (Thompson 2002). These activities are essential both to biosafety and to instill confidence that the government is independently ensuring safety, instead of relying on scientific researchers from industry or academia.

#### F. Summary

Consumers will have confidence in the products of agricultural biotechnology if consumer

trust the regulatory process for those products. As stated by the U.S. NRC in its report on EPA's regulation of biotech crops: "Ultimately, no credible evidence from scientists or regulatory institutions will influence popular public opinion unless there is public confidence in the institutions and mechanisms that regulate such products." (NRC 2000).

#### IV. Other Issues Important to Consumers

In addition to a strong regulatory structure, there are other factors that will affect a consumer's positive perception of agricultural biotechnology. First, as mentioned earlier, nothing will help this technology more than products with direct benefits to consumers. Although there may be no food-safety concerns with eating the current agricultural biotechnology products, consumers are unwilling to take even the smallest risk unless there is some benefit to them from a product. Consumers have embraced other products of technology such as drugs produced with biotechnology, computers, and cell telephones, all products consumers concluded have benefits that outweigh any risks.

A second area that will improve consumers' views on biotechnology would be a significant increase in public sector research. There needs to be independently funded research on risk assessment issues surrounding agricultural biotechnology. There should be research on minor crops that consumers eat in their daily diets but which are neglected by the biotechnology companies. Genetic engineering of these minor or orphan crops hold some of the best promise for consumer benefits, such as enhancing the iron content in rice or protein content in vegetable staples. (Pew 2001).

A third issue important to consumer's perception of agricultural biotechnology is ensuring access to biotechnology throughout the world. Mechanisms need to be put in place to share intellectual property between developed and developing countries. In addition to the transfer of intellectual property, there must be transfer of scientific knowledge, research and laboratory capacity, and biosafety capacity.

#### V. Role of Consumer Organizations

As a consumer organization, CSPI's role and the role of fellow consumer organizations throughout the world on agricultural biotechnology issues should be as follows:

- to educate consumers about the facts of biotechnology, including both the benefits and the risks;
- to get involved in the national and international debate about agricultural biotechnology;
- to act as a watchdog to ensure that industry and the government do their jobs to ensure that the products marketed are safe to humans and the environment;
- to support public activities relating to this technology, such as independent risk assessment research and public funding of research on minor crops; and
- to ensure that there is access to biotechnology for all societies that may find it beneficial.

#### VI. Conclusions

I would like to conclude with several observations about the future of agricultural

biotechnology. First, agricultural biotechnology is one of many tools available to move agriculture forward in the 21<sup>st</sup> century, both for developed and developing countries. It is not a panacea for all of the world's agriculture or food security problems but it may be useful to solve some of them. Although we should all strive for world-wide sustainable agriculture in the future, agricultural biotechnology is an immediate tool that can hopefully benefit some farmers, the environment, and consumers.

To properly utilize agricultural biotechnology, each country needs a strong, but not stifling, regulatory system to ensure that products are safe to humans and the environment. There is currently no country with an ideal regulatory system, although portions of many different country's systems are worth using as models for countries that are currently establishing a biosafety system. It is important that every country be given the opportunity to establish a biosafety system so that it can make its own determination whether a particular product meets its standards for safety. As stated by Per Pinstrup-Andersen, the Director General of International Food Policy Research Institute: "Condemning agricultural biotechnology for its potential risks without considering the alternative risks of prolonging the human misery caused by hunger, malnutrition, and child death is as unwise and unethical as blindly pursuing this technology without the necessary biosafety." Once a biosafety system is in place, two countries may rationally reach a different conclusion on the approval of the same product, due to a different balancing of the risks and benefits of that product to that country's population and environment. Each country needs a strong regulatory structure, however, to be able to make those decisions.

It is essential that regulatory systems be put in place that are transparent and allows for public participation. Unless the public is provided access to the system as well as detailed information about the products that go through it (including the basis for any approvals), there will be little public trust in the regulatory process and no consumer confidence in the marketed products. The key to reaping the long term benefits of agricultural biotechnology is a strong, but not stifling, regulatory system that independently reviews and approves each product for both food and environmental safety before it is released as a commercial product.

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