Creating the Proper Environment for Acceptance of Agricultural Biotechnology

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This paper consists of four sections. First, it describes the Center for Science in the Public Interest (CSPI) and its Biotechnology Project. Second, it discusses the current status of agricultural biotechnology in the United States, future trends for the technology and some of the controversy that surrounds it. Third, the paper discusses the current status and issues surrounding "biopharming," a major topic at this conference. The paper concludes with a discussion of what is needed for broader acceptance of agricultural biotechnology, not just in the United States but also abroad.

The Center for Science in the Public Interest

CSPI is a nonprofit consumer-advocacy organization that has focused on improving the safety and nutritional quality of our food supply. It 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. Its primary focus is on the United States, although it does have a satellite office in Canada. International activities involve food-safety and labeling issues, such as the *Codex Alimentarius* and the Trans-Atlantic Consumer Dialogue.

CSPI is primarily supported by the almost 900,000 member-subscribers to its *Nutrition Action Healthletter.* CSPI receives no funding from industry or the federal government; some funding comes from independent philanthropic foundations.

The Biotechnology Project

In 2001, CSPI began an advocacy project on agricultural biotechnology, the goals of which include to accurately identify risks and benefits of biotechnology, to ensure that the US regulatory system is up to the task of preventing significant risk, and to keep the public informed about the facts surrounding agricultural biotechnology.

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CSPI's biotechnology positions are based upon current evidence about the risks and benefits of biotechnology, not upon an ideological viewpoint that agricultural biotechnology is inherently good or bad. In 2001, based on its review of currently available evidence, CSPI stated that "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, 2001). Also, CSPI has stated on numerous occasions that currently engineered crops grown in the United States are yielding benefits to farmers and the environment by increasing yields and reducing the use of insecticides (CSPI, 2001; Jacobson, 2001a, 2001b; Jaffe, 2001). CSPI publicly acknowledges these beneficial applications and wants to ensure that they will continue to be realized. CSPI has been disappointed that other crops that could provide similar environmental benefits, such as Monsanto's NewLeaf ™ potato, have not been planted by farmers due to fear of a consumer backlash and a loss of market for the crop.

Of course, CSPI has also acknowledged that agricultural biotechnology has real risks that need to be assessed and addressed before products from genetically engineered (GE) crops are marketed. From the consumer's point of view, the key question about biotech foods is "Are they safe?" (Jaffe, 2004a). 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 (NRC, 2000, 2004; CSPI, 2001). Environmental risks are also possible from engineered crops. There is the potential for harm to non-target species, or the spread of the introduced gene and its characteristics to wild relatives of the transformed crop, or the development of pesticide resistance in insects or weeds (NRC, 2000; CSPI, 2001). Each possible environmental consequence needs to be thoroughly evaluated and adequately addressed before any biotech crop is released to the environment (Jaffe, 2004a).

Current Status of Agricultural Biotechnology and Future Potential Applications

In many ways, the past 10 years have been extremely successful for the biotechnology industry. Several blockbuster products were marketed in the 1990s, including soybeans, corn, cotton, and canola that are herbicide-tolerant and corn and cotton that produce their own insecticide that kills specific pests. Those GE crops have been widely adopted by farmers in the United States and, to a varying extent, in seventeen other countries around the globe. Over eight million farmers grew 200 million acres of GE crops in 2004 (ISAAA, 2005). From 1996 to 2004, the global acreage of transgenic crops increased 47-fold, from 4.2 million acres to approximately 200 million acres (ISAAA, 2005). In the

United States, 36.5 million acres of GE corn (45% of all corn) and 63.5 million acres of GE soybeans (85% of all soybeans) were grown in 2004 (USDA, 2004).

Those herbicide-tolerant and insect-resistant crops—biotechnology's "first generation"—have been found to be safe to humans and the environment in the United States. They have also provided benefits to farmers and the environment by increasing yields, reducing the use of insecticides or increasing farmer income.

Although the biotechnology industry's initial inventions have been quite successful, the introduction of new products with different traits has slowed considerably. In February, 2005, CSPI released a study, *Withering on the Vine: Will Agricultural Biotech's Promises Bear Fruit?* (Jaffe, 2005). That study analyzed publicly available data from federal regulatory agencies to determine whether the number of new commercial products has been increasing, decreasing or remained steady.

The study found that sixty-two biotech crops completed the Food and Drug Administration's (FDA) voluntary consultation process between 1995 and 2004 (Figure 1). In the first 5 years (1995 through 1999), forty-seven of those crops (an average of 9.4 per year) completed the regulatory process, whereas only fifteen crops (an average of three per year) completed the process in the next five years (2000 through 2004). Thus, the number of products per year completing the regulatory process plunged by 68% between 1995–1999 and 2000–2004. More than 75% of all biotech crops that have completed the FDA regulatory process did so between 1995 and 1999.

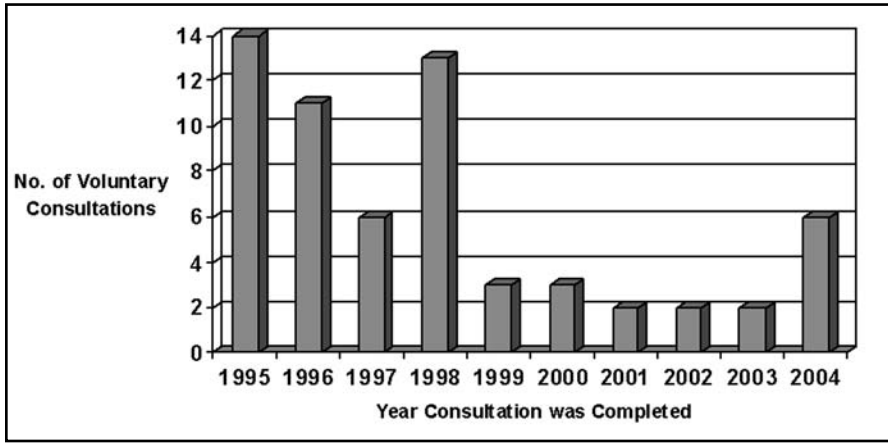

Figure 1. Genetically engineered crops completing FDA's voluntary consultation process (FDA, 2005).

Similarly, publicly available data about the granting of petitions for non-regulated status by the Animal and Plant Health Inspections Service (APHIS) of the United Stated Department of Agriculture (USDA) show a decreasing trend starting in 2000. From 1994 through 2004 (11 years), APHIS deregulated sixty-two biotech crops so that they could

be grown commercially without APHIS oversight. Forty-nine of those approvals occurred between 1994 and 1999 (an average of 8.2 per year) while only thirteen of those approvals occurred between 2000 and 2004 (an average of 2.6 per year) (Figure 2). Thus, APHIS approved almost four times as many crops from 1994 through 1999 than from 2000 through 2004. Clearly, the pipeline for new biotech crops has shrunk considerably, and few new products have become available for commercialization in recent years.

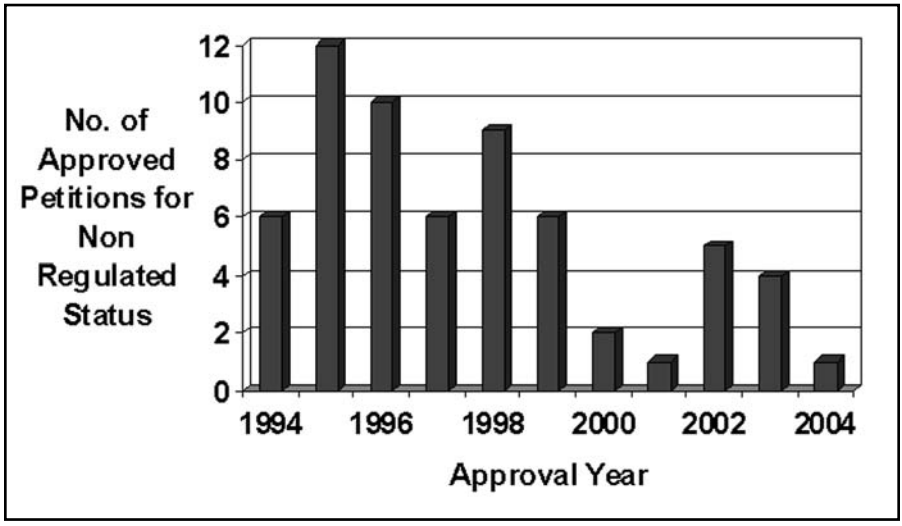

Figure 2. Genetically engineered crop petitions approved by USDA for non-regulated status (APHIS, 2005a)

The CSPI study also found that the GE crops that completed the regulatory process starting in 2000 tended to be variations of existing products with established and proven genes, rather than innovative applications of the technology. For example, of the fifteen consultations at FDA between 2000 and 2004, five involved Monsanto's placing in corn, wheat, creeping bent grass, canola, and sugar beet the same gene for resistance to the herbicide glufosinate ammonium (Roundup®) that was previously engineered into soybean and cotton and reviewed by FDA in 1995. Three applications of the fifteen involved engineering corn, rice, and cotton with a different gene (for phosphinothricin acetyltransferase) conferring herbicide tolerance that several companies had previously engineered into other crops that completed the FDA consultation process in the 1990s. The remaining seven GE products involved engineering corn and cotton with various *cry* genes from *Bacillus thuringiensis* that confer insect resistance. Although some of those applications could be considered "new" because they used *cry* genes not previously approved to address different plant pests, the *Bt* technology had been reviewed by FDA in consultations that go as far back as 1995. Therefore, in the past 5 years, the industry has not marketed a single new agronomic, nutritional, or other trait.

The CSPI study also looked at length of time to complete the regulatory reviews of engineered crops at FDA and APHIS, which it concluded has significantly increased between 2000 and 2004. For the sixty-two voluntary consultation reviews conducted by FDA, the submissions from 1995 through 1999 averaged 6.4 months for completion whereas the submissions from 2000 to 2004 averaged 13.9 months (Jaffe, 2005). Similarly, at APHIS granting a petition for non-regulated status took an average completion time of 5.9 months from 1994 to 1999, but an average of 13.6 months from 2000 to 2004 (Jaffe, 2005). Thus, it took the federal government twice as long to review biotech crops from 2000 to 2004 than it did in the 1990s, yet those products had no apparent novel considerations that might justify the longer reviews.

While the pipeline has slowed, international controversy over current engineered crops has continued. Whereas most governments and many distinguished scientists have found that those crops are safe, some people continue to be concerned with their safety to humans and/or the environment. Similarly, many opponents of genetic engineering do not believe that the current crops have any benefits, not just to consumers, but to farmers or the environment. Also, people throughout the world have called for the labeling of those crops and products from them, and many governments have imposed such labeling and traceability requirements (USDA, 2005).

The controversy over genetic engineering will only increase with the next generation of products.

The controversy over genetic engineering will only increase with the next generation of products. The biotechnology industry and university researchers in the United States and abroad have been inserting a wide range of engineered traits into many different organisms. While research on drought or salt tolerance may reduce the controversy over genetic engineering if they benefit small-scale farmers in developing countries, GE wheat and rice will likely increase the international controversy. Those applications are particularly controversial because those crops are grown primarily for human food needs, whereas the currently grown engineered corn and soybeans are primarily used for animal feed (Foreman, 2005). Similarly, applications of genetic engineering to animals to make faster growing salmon or improved cattle will be extremely controversial as they raise both safety and ethical issues (NRC, 2002a; Foreman, 2005). Finally, engineering plants to make pharmaceuticals ("biopharming") or industrial compounds is particularly worrisome when food crops are employed because no one wants to eat corn flakes with a pharmaceutical in them.

It is clear that those future applications of biotechnology may result in more controversy than the current crops. Already, the possibility that the next generation of products might come to market has sparked an increase in state legislation to hinder or prevent commercialization of those products. In the 2003–2004 legislative session, the Northern Plains states (Montana, North Dakota, and South Dakota) introduced legislation to curb the introduction of GE wheat, while Michigan, California and Alaska introduced

legislation to put limits on transgenic fish (Pew, 2005). In addition, Hawaii and Texas have introduced legislation limiting production of pharmaceuticals using food crops (Pew, 2005). Although the 2005–2006 legislative session has only just started, both Hawaii and Oregon have already introduced legislation on pharma crops. Thus, it is more important than ever to do whatever possible to ensure acceptance of those crops when they reach the marketplace.

Biopharming

Introduction

In the last couple of years, the biotechnology industry has engaged in genetically engineering plants to produce pharmaceuticals, industrial compounds, and other novel proteins ("biopharming" or "pharma crops") (Jaffe, 2004b). Products that manufacturers hope to market commercially include insulin from safflower, human serum albumin (used as blood volume replacement during shock, serious burns, and surgery) from corn, hepatitis B vaccine from tobacco, cholera and Norwalk virus vaccines in potatoes, and lactoferrin (a human protein that protects against infections) in rice.

For the 2004 growing season, USDA, which regulates the planting of pharma crops, received twenty applications to grow them in ten states. (Jaffe, 2004b). For the 2005 growing season, they received eighteen applications to grow them in seven states (APHIS, 2005a). Those applications involve the engineering of six different crops—corn, tobacco, safflower, barley, rice, and indian mustard—with corn, tobacco and rice constituting the majority of the applications (Figure 3).

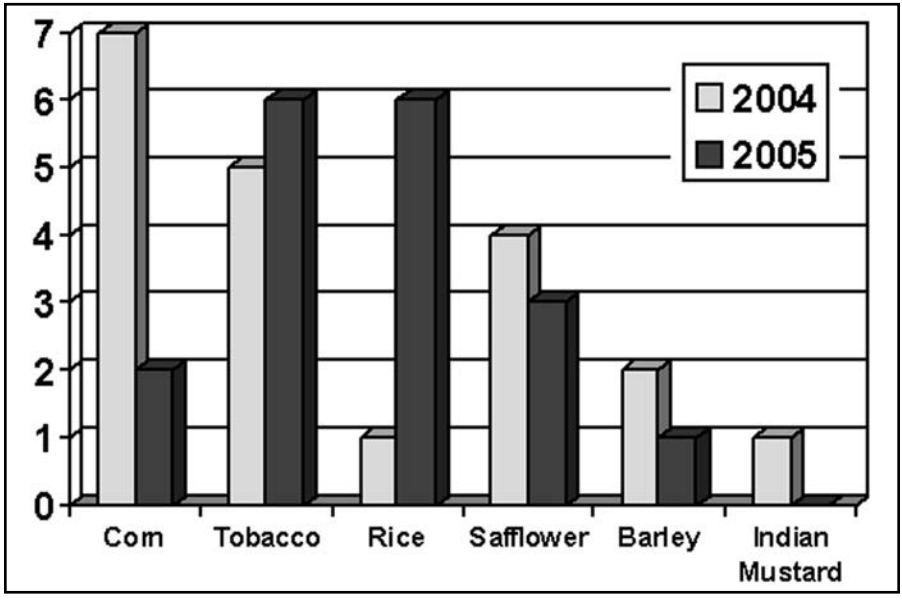

Figure 3. Biopharming permit applications for 2004 and 2005, by crop (APHIS, 2005b).

Although those applications of the technology have the potential to provide consumer benefits, if misused they could harm consumers or the environment. In fact, many scientists and other stakeholders believe that the risks from pharma crops are significantly greater than those from engineered crops grown for food purposes. The National Research Council stated the following in its report entitled *Environmental Effects of Transgenic Plants* about the potential risks of biopharming (NRC, 2002b):

> *Some of the coming applications of biotechnology may involve the issuing of plants to produce pharmaceutical products, biologics, fuels, and other substances not intended for human food use. The introduction of such transgenes poses the potential for environmentally associated risks of a* ***wholly different order*** *than those associated with existing transgenic crops. If such a transgene moves into food crops, either through pollen transfer or physical contamination, there could be* ***serious human safety risk.*** *If such a transgene moves into a wild relative, there could be widespread environmental dissemination of the pharmaceutical substance or other nonfood substances that* ***could have impacts on wildlife as well as microbial populations.*** (emphasis added)

While biopharming raises both environmental and food-safety issues, the controversy surrounding those crops has centered on the concern that they might inadvertently enter the food supply, causing either recalls of food products or rejection by international trading partners. That concern has caused industry stakeholders who normally support agricultural biotechnology to become advocates either against biopharming or for more stringent regulations. The Food Products Association has stated that it "has grave concerns about the use of bioengineered food and feed plants to produce non-food products" and that (FPA, 2003):

> *…given a voice during the early development of this promising technology, [FPA] would not have supported the use of food crops for the production of plant made pharmaceuticals.*

Similarly, the Grocery Manufacturers of America stated (GMA, 2003b):

> *The current US regulatory framework does not inspire confidence among our collective members that these drug and chemical crops will remain isolated and confined and not contaminate the food supply.*

In fact, it is as likely that an industry stakeholder will object to the planting of a pharma crop as one generally opposed to agricultural biotechnology. When the biopharming company Ventria Bioscience attempted to plant rice engineered to produce a pharmaceutical, Anheuser-Busch objected and was able to use its market power to alter where and under what conditions that rice would be grown (Bennett, 2005). Similarly, Agragen's announced intention to grow flax engineered to produce albumin in North Dakota, resulted in industry stakeholders such as AmeriFlax expressing opposition out of fear that, even without a contamination incident, their international markets for conventional flax will be jeopardized (Associated Press, 2005). Thus, it is clear that biopharming using

food crops is radically changing the debate surrounding agricultural biotechnology so that stakeholders who either supported or would support certain applications of genetic engineering, don't support biopharming in food crops.

Regulation of Biopharming and the USDA

A rigorous and robust regulatory system for ensuring that biopharm crops are safe for humans and the environment would do the following:[1]

- **Allow the planting of pharma crops only if the government issues a permit.** The regulatory system should put in place mandatory permitting requirements that must be complied with before the growing of any pharma crop. The permitting process should be transparent and allow public participation before the issuance of the permit.
- **Issue a permit only after a thorough environmental assessment of the potential risks from growing the pharma crop.** Before a permit is issued, the government should conduct a thorough environmental assessment of the potential effects of growing the pharma crop, including the effects from flow of the introduced gene and the effects of the transgenic protein on species other than humans.
- **Issue permits that require strict biological and physical confinement measures.** All permits should contain enforceable conditions requiring state-of-the-art confinement procedures. Those mandatory permit conditions should include isolation distances, geographic restrictions (such as not growing GE corn in parts of the country where commodity corn is grown), physical barriers (such as fences or greenhouses), the use of distinguishable varieties of the crop, biological confinement (such as male sterility), and so forth. The permit should also require extensive segregation and identity-preservation procedures that ensure that none of the harvested materials can commingle with crops destined for human or animal consumption. When using a food crop, the permit should have several redundant levels of confinement, even at the field-trial level.
- **Require regular inspections of the pharmaceutical-producing crop by the regulatory agencies.** As part of its regulation of pharma crops, both USDA and FDA should conduct regular, unannounced inspections of all facilities involved in the production of the pharmaceutical, from the laboratory to the farm to the manufacturing plant. Some of those inspections should occur after the crops have been harvested to prevent volunteer plants in future seasons. In addition, USDA and FDA should inspect neighboring fields and crops to confirm that containment has been achieved.
- **Require that if a pharmaceutical is produced in a food crop, there should be a mandatory pre-market food-safety approval process by FDA's Center for Food**

[1]The remainder of this article focuses on federal regulation of biopharming. It does not discuss state or local regulations, which could play a major role in overseeing the risks associated with pharma crops.

Safety and Applied Nutrition. Although confinement measures need to be strictly adhered to, they will never result in 100% containment over the long term. Thus, before any pharmaceutical is grown commercially in a food crop, FDA should conduct a thorough food-safety analysis to ensure that human exposure to the transgenic crop in the food supply would not result in any health risks. If additional legal authority is needed to implement this requirement, FDA and USDA should seek it from Congress.

Such a regulatory system would be able to protect human health and the environment, provide consumers confidence that their concerns are being adequately addressed, and lead to general acceptance of biopharming applications that are found safe. Unfortunately, the regulatory system for biopharming in the United States does not meet those minimum requirements.

The USDA regulates biopharming using its biotechnology regulations established under the authority of the Plant Pest Act (7 CFR 340). Under those regulations, a permit must be issued before any biopharm plant can be released into the environment. Applicants submit an application and USDA conducts some risk analysis of the proposed planting. USDA then issues a permit with specific confinement conditions and conducts inspections during the release to verify compliance.

The USDA permitting system for biopharming is not as rigorous, transparent, or protective as is needed to ensure safety for humans and the environment.

Unfortunately, the USDA permitting system for biopharming is not as rigorous, transparent, or protective as is needed to ensure safety for humans and the environment. First, it lacks transparency and the ability for the public to participate in many of the regulatory decisions. The non-confidential portion of the applications for biopharming permits are not made available to the public nor is any information about the general location or size of the release. Also, when the permit is issued, it is not made available to the public. In addition, the public is not informed about how many inspections are to be made at a particular site or the results of those inspections. Finally, there is no opportunity for public comment before the issuance of many biopharming permits. The public is given an opportunity to comment on a proposed permit only if an Environmental Impact Statement or Environmental Assessment is performed under the National Environmental Policy Act, which occurs in only a small minority of biopharming permits. In contrast, for every other engineered crop, before a petition for non-regulated status is granted (which is generally the last step before commercialization), the public is given the opportunity to comment on the regulatory decision.

Due to the lack of transparency in USDA's regulation of biopharming, it is difficult to assess whether or not their permitting system adequately protects the environment. The National Research Council reviewed some of the environmental assessments for transgenic food crops and found that they were not thorough and did not address broad ecological issues (NRC, 2002b). Some of the documents that have been released by USDA on their assessment of environmental issues surrounding biopharming have been extensive while others were extremely cursory. Thus, it is fair to state that USDA's environmental assessments for biopharming do not always thoroughly analyze gene flow, effects on non-target species, or any broad ecological effects of the transgenic plant.

Based on the documents released to the public about the permit conditions imposed on biopharming (USDA guidance as well as proposed supplemental conditions), the USDA does not require strict biological and physical confinement measures using state-of-the-art technologies. USDA primarily employs geographic and temporal separations and has not required biological confinement measures (*e.g.* male sterility or chloroplast transformation) nor geographic restrictions (such as not growing pharma corn in corn-belt states). Only by using all available confinement measures in a redundant fashion can both human and environmental health be safeguarded from biopharm crops.

Finally, although USDA has the legal authority to address agricultural and environmental issues surrounding biopharming, they have no Congressional mandate to address food-safety concerns. Under the Plant Protection Act, which USDA uses to promulgate its biotechnology regulations, there is no authority to safeguard the food supply. For this reason, USDA's permitting process does not involve any food-safety assessment of a pharma crop before it is released into the environment. USDA's assessment process does not determine whether the gene product will be harmful to humans if it enters the food supply. At the same time, FDA does not conduct any food-safety assessments of pharma crops. Thus, there is an extremely large gap in the federal government's regulation of biopharming where no agency assesses and addresses the food-safety risks of pharma crops.

The Need for FDA to Regulate Biopharming and Safeguard the Food Supply

The Federal Food Drug and Cosmetic Act regulates anything that is intended to be used as food or feed. However, a pharmaceutical corn plant or one producing avidin, for example, is not intended by the developer to be used as food or feed. Thus, those products are neither food additives, nor would they be subject to FDA's voluntary notification process (or FDA's proposed mandatory notification rule). FDA has limited authority over those products unless they show up in food. At that stage, FDA could consider foods containing the pharmaceutical compound (or industrial chemical) adulterated, and remove them from the market. The burden would be on FDA, however, to prove adulteration.

The current system is not the best way to ensure a safe food supply in view of the fact that contamination by pharma crops is inevitable. A possible solution to this problem would be for Congress to require a mandatory FDA approval process for all GE crops, both those intended for food use and pharma crops not intended for the food supply. Under that approval system, no GE food crop could be commercialized without a food-safety approval by FDA. For pharma crops to be commercialized, FDA would either need to

approve the crop as safe to eat or set a safe tolerance for the non-food substance. Then, if that GE crop entered the food supply, eating the engineered substance would be safe as long it was below the tolerance level; consumers would have no need to fear that they are eating unsafe food. In addition, the rigor of the food-safety assessment conducted by FDA should be proportionate to the physical and biological confinement of the crop. If the pharmaceutical crop is grown at a location far from other like plants, only a limited food-safety assessment might be required because the likelihood of contamination would be extremely small. If pharmaceutical corn is grown in Iowa, however, then a complete food-safety analysis might be warranted.

Providing FDA with mandatory authority to review the safety of pharma crops before they are released into the environment is not a far-fetched idea.

Providing FDA with mandatory authority to review the safety of pharma crops before they are released into the environment is not a far-fetched idea. As far back as 2002, a group of industry representatives at the Grain Quality Workshop concluded the following (Maier, 2002):

> *[We] urge the FDA that when future commercialization approvals of genetically modified grains and oilseeds for non-food and feed purposes are considered, these approvals also meet food safety requirements because inadvertent traces of these genetically modified grains and oilseeds will be detected in food and feed.*

The Grocery Manufacturers of America (2003a) also stated that pharma crops should not be grown:

> *…unless FDA has concluded that any release of the nonfood product into the food supply will be safe and that it will have no adverse effect on human health.*

Other countries have also included food-safety assessments for biopharming. In Canada, if a food or feed crop is used for biopharming (Canadian Food Inspection Agency, 2000):

> *…the developer must submit exposure and hazard data for human and livestock health effects assessment [by Health Canada].*

Finally, in the 107th Congress, Senator Richard Durbin from Illinois introduced the Genetically Engineered Foods Act (S. 2546). That bill would require all GE food crops to have a mandatory premarket approval before commercialization, including pharma crops. Therefore, many stakeholders agree that there are significant risks to the food supply from pharma crops and that a regulatory agency, such as FDA, needs to play a mandatory role in ensuring that those crops do not cause harm to humans.

The Road Forward for Acceptance of Agricultural Biotechnology

With the current state of affairs and the many controversial new applications on the horizon, agricultural biotechnology is unlikely to obtain broader societal acceptance in the near future. This will be particularly true for applications of the technology such as biopharming.

To create the proper environment for greater acceptance of agricultural biotechnology products, there should be the following:

- a strong, but not stifling, regulatory system that manages the potential risks of products using scientific risk assessments and state of the art technology;
- a regulatory system that is transparent and participatory;
- independent risk-assessment research that informs the public and regulators about the potential risks of particular applications and how to manage those risks;
- applications of the technology that provide direct benefits to consumers, both in developed and developing countries;
- broader access to the technology through the free licensing of intellectual-property rights to public-sector and developing-country researchers making products for the public good;
- involvement of the public early on in the development of products so that controversial and/or risky applications can be avoided.

The regulatory system must be transparent and participatory if it is to engender trust among consumers.

Agricultural biotechnology is one of the many tools available to move agriculture forward in the twenty-first century. It can provide beneficial products, including pharmaceuticals. To properly utilize biotechnology, however, the regulatory system must ensure that products are safe for humans and the environment. That system must be transparent and participatory if it is to engender trust among consumers. Only then will there be an environment in which consumers will embrace safe applications of biotechnology.

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As an expert on the US regulatory structure for agricultural biotechnology as well as related consumer issues, Mr. Jaffe has published articles in *Transgenic Research,* the *Sacramento Bee, St. Louis Post-Dispatch, Christian Science Monitor*, the Food and Drug Law Institute's *Update* magazine, the Environmental Law Institute's *Environmental Forum* Magazine, and has spoken at numerous national and international conferences.

He was appointed in 2003 to Secretary of Agriculture Veneman's Advisory Committee on Agricultural Biotechnology and 21st Century Agriculture and in November, 2004, to the Food and Drug Administration's Veterinary Medicine Advisory Committee. He is also a member of the governing Bureau for the International Assessment of Agriculture Science and Technology for Development and the Advisory Board for the International Society for Biosafety Research.

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