"Creating the Proper Environment for Acceptance of 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 biotechnology's most pressing issues and allow safe applications to be commercialized.

This paper consists of four separate sections. First, this paper 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, the 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. Finally, the paper concludes with a discussion about what is needed for broader acceptance of agricultural biotechnology, not just in the United States but also abroad.

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

CSPI is a nonprofit consumer-advocacy organization that has focused on improving the safety and nutritional quality of our food supply. 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 almost 900,000 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.

A. CSPI Biotechnology Project

In 2001, 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.

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. CSPI stated in 2001 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, 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 pesticides. (Jaffe, 2001; Jacobson, 2001a; Jacobson, 2001b; CSPI, 2001) 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 New Leaf 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 also 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?" (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. (CSPI, 2001a; NRC, 2000; NRC, 2004) There are also possible environmental risks 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, 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. (Jaffe, 2004a)

II. Current Status of Agricultural Biotechnology and Future Potential Applications

In many ways, the past ten years have been extremely successful for the biotechnology industry. The industry marketed several blockbuster products in the 1990s. Those products include soybeans, corn, cotton, and canola that are herbicide-tolerant and corn and cotton that produce their own pesticide that kills specific pests. Those genetically engineered (GE) crops have been widely adopted by farmers in the U.S. and to varying extent in 17 other countries around the globe. Over 8 million farmers grew 200 million acres of GE crops in 2004. (ISAAA, 2005) From 1996 to 2004, the global acreage of transgenic crops has 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 - also called biotechnology's "first generation" - have been found to be safe to humans and the environment in the U.S. They have also provided benefits to farmers and the environment by increasing yields, reducing the use of pesticides or increasing farmer income.

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

The CSPI study found that 62 biotech crops completed FDA's voluntary consultation

process between 1995 and 2004 (See Figure 1)(**Please Insert Figure 1**). In the first five years (from 1995 through 1999), 47 of those crops (an average of 9.4 per year) completed the regulatory process, while only 15 crops (an average of 3 per year) completed the process in the next five years (2000 to 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.

Similarly, publicly available data about the granting of petitions for non-regulated status by APHIS show a similar decreasing trend starting in 2000. From 1994 through 2004 (11 years), APHIS deregulated 62 biotech crops so that they could be grown commercially without APHIS oversight. 49 of those approvals occurred between 1994 and 1999 (an average of 8.2 per year) while only 13 of those approvals occurred between 2000 and 2004 (an average of 2.6 per year) (See Figure 2) (Please Insert Figure 2). Thus, APHIS approved almost four times as many crops from 1994 through 1999 than from 2000 to 2004. Clearly, the pipeline for new biotech crops has shrunk considerably, and few new products have become available for commercialization.

The CSPI study also found that the GE crops that completed the regulatory process starting in 2000 tend to be variations of existing products with established and proven genes, rather than new, innovative applications of the technology. For example, of the 15 consultations at FDA between 2000 and 2004, five of them involved Monsanto's placing in corn, wheat, creeping bent grass, canola, and sugar beets the same gene for resistance to the herbicide glufosinate ammonium (Round Up) that was previously engineered into soybeans and cotton and reviewed by FDA in 1995. Three applications of the 15 involved engineering corn, rice, and cotton with a different gene for herbicide tolerance (the "phophinothricin actyltransferase" or "PAT" gene) 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 different Cry genes from the microorganism, 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 back as far as 1995. Therefore, in the past five years, the industry has not marketed a single new agronomic, nutritional, or other trait.

The CSPI study also looked at the length of time that it takes to complete the regulatory reviews of engineered crops at FDA and APHIS, which it concluded has significantly increased between 2000 and 2004. For the 62 voluntary consultation reviews conducted by FDA, the submissions from 1995 through 1999 averaged 6.4 months to completion while the submissions from 2000 to 2004 averaged 13.9 months to completion. (Jaffe, 2005) Similarly, at APHIS granting a petition for nonregulated status took a average completion time was 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, the international controversy over the current engineered crops has continued. While 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 produced 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 biotechnology industry and university researchers in the United States and abroad have been working on 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 be used as factories to make pharmaceuticals or industrial compounds (called "biopharming") 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 the marketing of those products. In 2003-4 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 introduced legislation limiting production of pharmaceuticals using food crops. (Pew, 2005) Although the 2005-6 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.

III. Biopharming

A. 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, 2004) Potential products that manufacturers hope to produce 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 those pharma crops,

received 17 applications to grow those crops in 10 different states. (Jaffe, 2004) For the 2005 growing season, they have received 21 applications to grow such crops in 7 different states. (APHIS, 2005) 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. (**Please Insert Figure 3**)

While 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 the engineered crops grown for food purposes. The National Research Council stated in its report entitled "Environmental Effects of Transgenic Plants" the following about the potential risks of biopharming:

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**. (NRC, 2002) (emphasis added)

While biopharming raises both environmental and food safety issues, the controversy surrounding those crops has centered around the concern that they might inadvertently enter the food supply, either causing 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 and plant materials to produce non-food products," and that "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." (FPA, 2003) Similarly, the Grocery Manufacturer's Association stated that "The current U.S. 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." (GMA, 2003)

In fact, it is as likely that an industry stakeholder will object to the planting of a pharma crop as a stakeholder who is 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, now that Agragen has announced that it will try to grow flax engineered to produce albumin in the future in North Dakota, industry stakeholders such as AmeriFlax are opposing such plans because they are afraid that even without a contamination incident, their international markets for conventional flax will be put in jeopardy. (Associated Press, 2005) Thus, it is clear that biopharming using food crops is radically changing the debate surrounding on agricultural biotechnology so that stakeholders who either supported or would support certain applications of genetic engineering, don't support biopharming in food crops.

B. 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

- 1. Only allow the planting of pharma crops 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 for public participation before the issuance of the permit.
- 2. Only issue a permit 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 gene flow of the introduced gene and the effects of the transgenic protein on living species other than humans.
- 3. <u>Issue permits that require strict biological and physical confinement</u> 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 procedures that ensure that none of the harvested materials can co-mingle 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.

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

- 4. Require regular inspection of the production of the pharmaceutical in the plant 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 plants. Those inspections should occur after the crops have been harvested to prevent volunteer plants in future seasons. In addition, USDA and FDA should also inspect neighboring fields and crops to confirm that containment has been achieved.
- 5. Require that if a pharma crops is grown in a food crop, there should be a mandatory pre-market food-safety approval process by FDA's Center for Food Safety and Applied Nutrition. Although confinement measures need to 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 will not result in any health risks. If additional legal authority is needed to implement this requirement, FDA and USDA should ask Congress to provide such authority.

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 the biopharming applications found safe. Unfortunately, the regulatory system for biopharming in the United States does not meet those minimum requirements.

The United States Department of Agriculture 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 does conduct some risk analysis of the proposed planting. USDA then issues a permit with specific confinement conditions and conducts some inspections during the release to ensure that the permit is being adhered to.

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, the USDA regulatory system for biopharming 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 are any information about the general location and 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 made at a particular site and the results of those inspections. Finally, there is no opportunity for public comment before the issuance of many biopharming permits. The public is only given an opportunity to comment on an a proposed permit if an Environmental Impact Statement or Environmental Assessment is performed under the National Environmental Policy Act. That occurs in a small minority of the biopharming permits. In contrast, for every other engineered crops, before a petition for non regulated status is granted (which is generally the last step before commercialization of a crop), 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 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, 2002) Some of the documents that have been released from USDA on their assessment of addressing environmental issues surrounding biopharming have been extensive while others are extremely cursory. Thus, it is fair to state that USDA's environmental assessment for biopharming do not always thoroughly analyze gene flow, effects on nontargets, and 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 the 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 separation but 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 humans and the environment be safeguarded from biopharm crops.

Finally, while USDA has the legal authority to address agricultural and environmental issues surrounding biopharming, they have no Congressional mandate to address the food safety concerns. Under the Plant Protection Act, which USDA used to promulgate it 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 the 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 does enter the food supply. At the same time, the Food and Drug Administration also does not conduct any food safety assessment of pharma crops. Thus, there is an extremely large gap in the federal government's regulatory of biopharming where no agency assesses and addresses the food safety risks of a pharma crop.

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

The Federal Food Drug and Cosmetic Act ("FFDCA") regulates anything that is intended to be used as food or feed. A pharmaceutical corn plant or a corn plant producing avidin, however, 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 drug or industrial chemical adulterated and remove them from the market. The burden would be on FDA, however, to prove they are adulterated.

That current system is not the best way to ensure a safe food supply, when contamination by non-food GE crops growing pharmaceuticals 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 crop grown in a 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 as the substance was below the tolerance level. No consumers would need to fear that they were eating food with unsafe substances in it. 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 plant was grown in a cave or a location far from other corn plants, only a limited food-safety assessment might be required because the likelihood of contamination would be extremely small. If the pharmaceutical plant was 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. As far back as 2002, a group of industry representatives at the Grain Quality Workshop concluded the following: "To 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 inadvertently traces of these genetically modified grains and oilseeds will be detected in food and feed." (Maier, 2002). The Grocery Manufacturer's Association 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 – that it will have no adverse effect on human health." (GMA, 2003a).

Other countries have also included food safety assessments for biopharming. The Canadians include in their regulations that if one uses a food or feed crop for biopharming, "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.

IV. The Road Forward for Acceptance of Agricultural Biotechnology

With the current state of agricultural biotechnology and the many controversial new applications on the horizon, obtaining broader societal acceptance of agricultural biotechnology will not be easy. 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 in both developed and developing countries;
- Broader access to the technology through the free licensing of intellectual property rights to public sector and developing country researchers producing products for the public good;
- Involvement of the early on in the development of products so that controversial and/or risky applications can be avoided.

Agricultural biotechnology is one of the many tools available to move agriculture forward in the 21st century. It can produce beneficial products, including products such as pharmaceuticals. To properly utilize biotechnology, however, there must be a strong, but not stifling, regulatory system that ensures that products are safe to humans and the environment. That system must be transparent and participatory if consumers are to trust both the regulatory system and the decisions it makes. Only then will there be the proper environment for consumers to embrace safe applications of biotechnology.

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