
Potential Concerns of Different Stakeholders to Genetically Engineered Specialty Crops

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This presentation has two separate sections. The first attempts to summarize and explain some potential concerns that different non-governmental stakeholders might have with genetically engineered (GE) specialty crops. It is based upon a review of publicly available written documents from those organizations and review of their internet websites, and does not reflect my views or the views of Center for Science in the Public Interest. The second section of the presentation is the Center for Science in the Public Interest's view on some issues that GE specialty crop developers should consider as they develop those crops and bring them to market.

PRODUCT-SPECIFIC CONCERNS

When preparing this presentation, I looked for product-specific concerns—related to GE specialty crops—that have been voiced by different organizations. Surprisingly, I found few concerns related specifically to specialty crops. I looked through the dockets on the GE plum and the GE apple¹ at USDA and searched websites of stakeholder groups and found that most of the concerns raised are not related to specific applications.

I did find some specific concerns over a virus-resistant plum, which has been approved but is not yet commercialized. The Organic Consumer Organization had doubts over the stability of the inserted genes and raised concerns over potential effects on bees and other pollinators. With other organizations, they pointed out the absence of short- and long-term safety testing and feeding trials for toxicity and other effects. The Sierra Club also was fairly vocal at that time, and they raised some issues around potential harm to local bee communities. They suggested the potential for creation of new viral forms via

¹Pages 87–94.

recombination, and even doubted the safety of eating viral proteins. Many would take issue with the validity of these concerns; I mention them to illustrate the kinds of product-specific questions that have been raised.

The initial public-comment period that is part of the on-going review of the GE apple elicited the following concerns from the Center for Food Safety in Washington, DC:

- Changes in resistance to pests and pathogens may occur as a result of the suppression of polyphenol oxidases.
- Cut and packaged apple slices may support the growth of pathogenic microorganisms.
- The nutritional status of the cut apple slices may be unpredictably affected by storage and packaging conditions.

GENERAL CONCERNS

I was surprised to discover that many of the objections to specialty crops are not product-specific. Instead, they are what I call generic concerns—objections to GE crops in general rather than to any specialty crop in particular. Similar objections could be leveled at corn, soybean, apple, plum, broccoli or whatever. I won't attempt an exhaustive coverage; I did look at the website of the Center for Food Safety to examine their concerns regarding food safety for GE crops in general. They posed the question, "What are the new 'unexpected effects' and health risks posed by generic engineering?" and answered it by listing six areas:

- Toxicity
- Allergic reactions
- Antibiotic resistance
- Immuno-suppression
- Cancer
- Loss of nutrition

They explained why they thought that each of these could be linked to genetic engineering. They had similar information for the environmental area, but this provides a good example of what consumers are hearing from this group regarding the safety of GE ingredients in food.

Food and Water Watch, an environmental group, issued a report in 2011, *Genetically Engineered Foods: An Overview*, providing their perspectives on GE foods. The following are quotes from the overview, illustrating their concerns over GE crops and the foods made from them:

Genetic contamination is a serious threat to the livelihoods of non-GE and organic farmers who bear the financial burden of these incidents.

The environmental effects of GE crops can include intensified agrochemical use and pollution, increased weed and insect resistance to herbicides and pesticides, and gene flow between GE and non-GE crops.

The Roundup Ready trait lowers the nutritional content of crops by inhibiting the absorption of nutrients, including calcium, iron, magnesium and zinc, making the plants more susceptible to disease.

The second statement reflects a commonly expressed concern that the environmental effects of GE crops include increased agrichemical use and pollution, increased resistance of weeds and insects to herbicides and pesticides, and the likelihood of gene flow between GE and non-GE crops. I had never come across the third statement before. Many other concerns are provided in that report; these three provide just a “flavor.”

OPENING THE FLOODGATES

Now I come to even more general concerns. One that appears frequently in literature from consumer and environmental NGOs is the idea of “precedent,” that approval of a particular GE crop will somehow “open the floodgates.” A quote from one of these is:

This is simply a Trojan horse to get more GE foods and crops on the market.

The Organic Consumer Association expressed it thus:

The approval of GE plums would be a precedent-setting step by the USDA opening the floodgate for more GE trees including fruit, nut, ornamental and paper-pulp species as well as trees engineered for soil remediation and other traits.

Similarly, people expressed opposition to GE alfalfa during the deregulation process, on the grounds that it would set a precedent. So that’s an argument that one needs to be aware of in this field.

CONTAMINATION

From the Sierra Club:

The organic and conventional plum markets in the United States will quickly be threatened by the first GE plum tree that will contaminate organic and conventional plum orchards once it is approved...

This espouses the notion that GE crops will “contaminate” organic and conventional crops.

A similar doomsday scenario has been suggested by Friends of the Earth and Food & Water Watch:

There could be significant economic impacts to conventional and organic orchards if their apples are contaminated with GE apples...

Concerns over co-existence and contamination are commonly raised with respect to GE corn, and somewhat less so with respect to GE soybean.

MANDATORY LABELING

The demand for mandatory labeling of foods containing GE ingredients is another general issue raised for all GE products, including specialty crops. It has become a vocal movement in numerous states, having started in 2012 with the California Ballot Initiative, which

didn't pass but garnered national press and publicity. Much of the discussion underpinning it revolves around the issue of "right to know": consumers have the right to know what's in their food. A second issue surrounding those calling for mandatory labeling is that they say consumers are not sure that GMO food is safe so it should be labeled so that they can choose not to eat it. A third argument is often seen: if it is safe and beneficial, why hide it? I raise this because it could become a greater issue for specialty crops—which are consumed directly—than for corn or soybean, considering that the latter crops enter the human food chain mainly as highly processed ingredients such as corn oil, soy lecithin, high-fructose corn syrup, *etc.*

The Genetically Engineered Foods Right-to-Know Act, introduced in April 2013 by Senator Barbara Boxer from California and Congressman Peter DiFazio from Oregon, is a bellwether for the labeling issue. It would require labeling on whole foods and processed foods including fish and seafood. According to Senator Boxer:

Americans have the right to know what is in the food they eat so they can make the best choices for their families. This legislation is supported by a broad coalition of consumer groups, businesses, farmers, fishermen and parents who all agree that consumers deserve more—not less—information about the food they buy.

This statement is true of lots of things, not just genetic engineering.

Figure 1 shows the status of state-level food-labeling bills in June, 2013. The states in blue have bills proposed. Those in red have some approved. In New York in June, 2013, a food-labeling bill was voted down in committee. In contrast, the governor of Connecticut has stated his intention to sign a GE food-labeling bill, which has gone through both houses. However, it won't come into play until a certain number of neighboring states have enacted similar legislation. The implication is that Connecticut would be economically disadvantaged if it were the only state in the region with GE-food labeling.

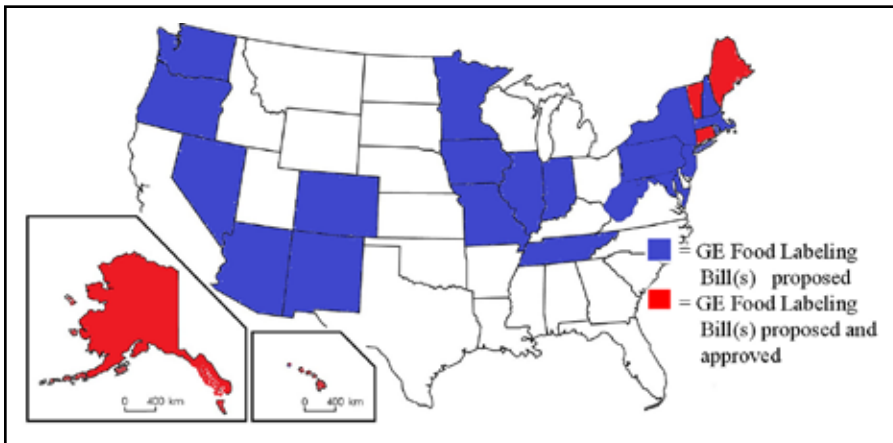


Figure 1. State-level GE food-labeling bills.

CSPI'S VIEWS

The Center for Science in the Public Interest is a non-profit consumer organization located in Washington, DC working on food and nutrition issues. We advocate based on the best available science on behalf of consumers and try to educate consumers on the relationship between their health, their diet, and the food they eat. Our Biotechnology Project started in 2001, and we are devoted to reviewing the evidence and facts surrounding the GE crops grown in the United States. We have found that scientific evidence supports their safety, both to grow and to eat. The evidence also points to benefits accruing from growing some of those crops, either to farmers or to the environment, but not necessarily directly to consumers.

On the other hand, CSPI does believe that GE crops need to be assessed on a case-by-case basis, and we do push for functional biosafety regulatory systems that ensure safety while allowing safe products to be marketed. CSPI is supportive of streamlining regulations, where appropriate. The idea would be to have the regulatory system look carefully at crops and traits that are less familiar and potentially risky with more scrutiny, while facilitating deregulation of familiar and safe crops and traits in a streamlined fashion.

For those developers who wish to market GE specialty crops, CSPI believes there are two critical areas needed for overall product success with consumers in the marketplace. The first is ensuring there is comprehensive federal regulation and oversight that ensures consumers that the GE specialty crops are safe to eat and safe for the environment. Second, the developer must anticipate and address both consumer and customer acceptance issues, which involve market acceptance, coexistence, and transparency. These two critical issues will be discussed in detail below.

COMPREHENSIVE FEDERAL OVERSIGHT

By “comprehensive federal oversight” I mean:

- A statement from FDA that the GE crop variety in question is safe to eat,
- A full review by the USDA with necessary environmental analysis under the National Environmental Policy Act, and
- Appropriate risk assessment—what many in the industry might call “stewardship.”

FDA

The Food and Drug Administration regulates crops, including fruits and vegetables, under the Federal Food, Drug and Cosmetic Act, under which “food additives” go through a pre-market approval process, unless they are generally recognized as safe (“GRAS”). FDA determined that a GE crop is not a food additive and in 1992 set up a voluntary consultation process for GE plants to ensure that the GE plant was “substantially equivalent” to its conventional counterpart. To date, all those who have commercialized GE crops have complied with voluntary consultation. However, in view of the fact that food safety is a critical issue for consumers, we at CSPI are of the opinion that the voluntary consultation process is not sufficient. The reviews by FDA are not comprehensive. More importantly,

their stock response—“we have no questions at this time”—implies that Monsanto, or whoever is developing the product in question, remains responsible.

We believe that safety determinations by FDA are needed. When the GE-wheat issue hit in Oregon in May 2013, the most that could be offered by USDA in their press release was the wishy-washy comment that FDA had looked at it and had no questions at that time on its safety. Other countries have mandatory pre-market food-safety approval processes, and it's ironic that, in the United States, none of these crops can be planted without a mandatory review by USDA, yet we can eat the food from them without that. In 2004, Senator Durbin introduced the Genetically Engineered Foods Act—reasonable legislation in this area; it would take the voluntary process and mandate it without changing the safety standard or the data requirements. The FDA would formally approve the safety of each GE crop. It would not lengthen the process but it would give consumers confidence in the federal government's oversight. Support from those who are developing GE crops would help alleviate concerns both around labeling and the technology.

USDA

The United States Department of Agriculture needs to be involved in overseeing regulation of these crops to ensure against agricultural and environmental problems. The USDA's (non)position on herbicide-tolerant Kentucky blue grass—a GE variety developed by Scotts Corp.—is revealing. In 2010 Scotts requested a determination of the regulatory status of GE (glyphosate tolerant) blue grass; none of the DNA cassette (donor gene, promotor sequence, *etc.*) were plant pests and the gene gun was used to achieve transfection rather than *Agrobacterium*. Accordingly, the USDA responded in 2011 that this GE crop is not regulated.

I have been arguing for about ten years that the USDA regulatory system may not apply to some GE crops and now we actually have a decision by USDA that they will not regulate this crop. So, this GE Kentucky blue grass can be field-tested without any oversight, and it can go to market without any oversight. I raise this because some may be thinking, “Regulation is expensive. It takes time. We should do what Scotts did.” I would counsel against that for specialty crops. You need USDA oversight to garner consumer confidence and achieve market acceptance. At the same time, USDA needs to do a better job. There has been litigation over glyphosate-tolerant alfalfa and sugar beets, where courts have said that the USDA environmental analyses under the National Environmental Policy Act were lacking. In response to that, USDA now is in part doing an environmental impact statement (EIS) for the 2,4-D- and dicamba-tolerant crops. It is fundamentally important that USDA does its job well, that they assess environmental impacts, and that they avoid litigation. They don't need EISs in all cases or even in most cases, but they need to do a better job. They had gotten sloppy for a number of years, and the courts properly slapped them on the wrist. They have a new system in place that will, hopefully, be quicker and do a better job.

Finally, USDA needs to insist on appropriate stewardship. There's evidence of resistance to *Bt* in corn rootworms and of herbicide-tolerant weeds, possibly resulting from poor stewardship by farmers and some biotech companies. This technology has the potential

to be very beneficial for specialty crops. It should be used judiciously and as appropriate, depending on the biology of the specialty crop, with appropriate management practices to minimize the development of insect resistance to *Bt* and other insecticides, and to minimize the development of herbicide resistance in weeds.

ANTICIPATING CONSUMER ACCEPTANCE

The second issue is to anticipate and address consumer and customer acceptance, which involves:

- Market acceptance
- Coexistence
- Transparency—right to know

Market Acceptance

To achieve market acceptance of a product, there is need to educate, inform and listen to the farmers and relevant farm organizations. There is need to listen to food-chain actors and to educate them, including grocery stores, as well the media, regulators and politicians.

Coexistence

Coexistence is the concurrent cultivation of biotech, organic, and non-biotech varieties of the same crop. It depends on the biology of the crop and the production system. It is different for corn than for soybeans than for apples. It requires setting up appropriate processes in the food chain. I raise this issue because it may be increasingly important in the future, depending on the crop. We saw this in terms of concerns raised by environmental consumer groups at the beginning of this presentation, and I think it's important to put in place procedures to segregate seed. Any inadvertent commingling will have minimal effect as long as there's a segregated seed supply. To me, that is key.

Transparency

Finally, on the transparency issue, CSPI is not in favor of mandatory GE labeling. We do think that there should be consumer access to information about whether their product is genetically engineered, so for the consumer who wants to know, they should be able find it. It shouldn't be hidden, but that's different from having a mandatory government-imposed label. We do think that that information should be available whether it's on a website or electronically; there's a host of different ways to make information available these days. But, with that, there needs to be information about the benefits of these products, as well as information about the production process. Consumers don't know a lot about how their food is produced or where it comes from, so hearing "genetic engineering" out of the agricultural context can be confusing. There needs to be better education and transparency all around.

IN CONCLUSION

We need strong, but not stifling, regulation to reassure consumers. I call it "appropriate regulation." It can be streamlined by using preexisting data. There is no reason to reinvent the wheel, but the primary emphasis should be on issues that pose the greatest potential

risk and issues that are most unfamiliar. We want beneficial products and education to explain those benefits and their production process. I think that's really important. People don't know a lot about the quantities of pesticides used in producing unblemished fruits and vegetables. If they did understand that, there might be a different view about using technologies to reduce agriculture's environmental footprint. As I said, transparency is essential but not necessarily mandatory labeling. It is more important to be aware of general concerns related to GE crops. Genetically engineered specialty crops are not going to be treated differently by consumers who have concerns or objections to GE in general.

FURTHER READING

Jaffe G (2012) Straight Talk on Genetically Engineered Foods: Answers to Frequently Asked Questions. <http://cspinet.org/new/pdf/biotech-faq.pdf>.

Jaffe G (2013) What You Need to Know About Genetically Engineered Food. http://cspinet.org/new/pdf/what-you-need-to-know-about-genetically-engineered-food-the_atlantic-feb-2013.pdf.



GREGORY JAFFE is director of the biotechnology project for the Center for Science in the Public Interest (CSPI), an advocacy and educational organization that focuses on nutrition and health, food safety, alcohol policy, and sound science. CSPI was instrumental in pushing through the federal law to create the Nutrition Facts label with clear nutrition information and that set standards for nutrition and health claims on food labels. CSPI is supported primarily by 800,000 subscribers to its Nutrition Action Healthletter.

Mr. Jaffe first worked as a trial attorney for the US Department of Justice's Environmental and Natural Resources Division for seven years. He then moved on to become senior counsel with the US Environmental Protection Agency Air Enforcement Division, before joining CSPI to direct the biotechnology project. He is a recognized expert on the US regulatory structure for agricultural biotechnology as well as consumer issues pertaining to agricultural biotechnology.

He earned his BA from Wesleyan University in biology and then received a degree from Harvard Law School.