Update 2007, Issue 1
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Regulating Transgenic Crops

Is Government Up to the Task?

by William Freese

On August 18, 2006, the U.S. Dept. of Agriculture (USDA) announced that an unapproved variety of genetically modified (GM) rice developed by Bayer CropScience had widely contaminated U.S. rice supplies. In the following months, the illegal rice was detected in U.S. rice exports to numerous countries, resulting in rejected shipments and dramatically lower rice prices, and leading scores of farmers to sue Bayer for lost earnings—by some accounts, up to $150 million. Bayer says it stopped development of the variety—LibertyLink 601—in 2001. Nearly four months later, USDA still does not understand how the contamination occurred. Ironically, USDA recently cleared this unmarketable rice for commercial use in a controversial decision widely criticized as setting an unhealthy "approval-by-contamination" precedent. And Bayer has since received USDA authorization to conduct nine new field trials of GM crops.[1]

This episode, following many similar ones in the past, has renewed questions about the ability and willingness of the U.S. government to adequately regulate transgenic crops.

The need for regulation is clear. Genetic engineering or modification involves splicing genetic material from bacteria, viruses, and other organisms into plant genomes to endow plants with novel traits, most commonly the ability to survive application of an herbicide that would otherwise kill the (non-engineered) plant.[2] This represents a radical departure from traditional plant-breeding, which relies on crossing members of the same or closely related species to improve characteristics like yield. One class of risks arises from the novel trait itself. These include the unresolved potential for allergic reactions from consumption of bacteria-derived insecticidal proteins introduced into GM corn to repel pests; harm to "non-target" insects such as the Monarch butterfly; and the creation of more problematic weeds associated with herbicide-tolerant (HT) crops.[3]

A second class of largely unexplored risks arises from extensive mutations to plant genomes caused by the haphazard and mutagenic engineering process,[4] which can disrupt plant metabolism, potentially leading to generation of harmful new compounds, increased levels of native plant toxins, or decreased nutritional content.[5]

So how are GM crops regulated in the U.S.? The foundations were laid in the 1980s and 1990s by the Office of Science and Technology Policy and the Council on Competitiveness, both White House agencies. They declared that GM crops and foods were *not* fundamentally new, and could be regulated under existing statutes designed for plant pests, chemical pesticides, and food additives. In other words, use of the radical new genetic engineering techniques *per se* would not trigger any special regulatory consideration. Biotech industry and government officials have testified to the tremendous influence exerted by industry (particularly the Monsanto

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Company) on the formulation of this policy, which was designed to speed transgenic crops to market, while at the same time reassuring consumers that GM foods had passed government review. According to Henry Miller, in charge of biotechnology at the Food and Drug Administration (FDA) from 1979-1994: "In this area, the U.S. government agencies have done exactly what big agribusiness has asked them to do and told them to do."[6]

Regulation of genetically engineered foods is divided among three federal agencies.

- USDA oversees GM crop field trials and is responsible for deregulating (i.e., permitting the unregulated cultivation of) GM crops under the Plant Protection Act (PPA).
- The Environmental Protection Agency (EPA) has jurisdiction over the pesticides incorporated in GM insect-resistant plants under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FDCA); and
- FDA conducts voluntary consultations on other aspects of GM foods with those companies that choose to consult with it, under the FDCA.

USDA

At the experimental stage, GM crops are nominally considered "plant pest" risks under the PPA,[7] and hence cannot be released (planted outdoors) without prior approval by USDA's Animal and Plant Health Inspection Service (APHIS). Such approval, however, is now granted routinely. APHIS has authorized roughly 50,000 field tests of experimental GM crops on over half-a-million acres since 1987. The great majority (95 percent in 2004) have taken place under a streamlined "notification" system introduced in 1993.[8]

Under this system, the crop developer sends APHIS a notification of its intent to conduct a field test, noting the size and location(s) of the trial, and the genetic materials and methods employed to develop the GM crop. APHIS then notifies the pertinent state department of agriculture, and normally issues an "acknowledgement" within 30 days. A somewhat more involved permitting process is reserved for trials involving crops engineered to produce pharmaceuticals or industrial compounds. Each notification or permit is limited to only one crop, but often encompasses: a) several to dozens of different genetic modifications; b) multiple field tests in several to dozens of states; and c) anywhere from fractions of an acre to thousands.[9] APHIS virtually never conducts an environmental assessment prior to issuing "acknowledgements" or permits. The convenient fiction—abundantly disproven by reality—is that field tests are "confined releases" whose impacts need not be assessed because the GM crop pollen and seed will not escape the bounds of the field test site(s).

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APHIS has established guidelines (performance standards) for field trials with the goal of minimizing gene flow to, and inadvertent mixing with, conventional crops and weeds. However, a long and growing string of contamination episodes underscores the inadequacy of APHIS oversight.[10] The agency has come in for often harsh criticism. A 2002 report by the National Academy of Sciences (NAS) identified numerous deficiencies such as lack of transparency, too little external scientific and public review of decisionmaking, poorly trained personnel, and allowing companies to make excessive claims of confidential business information (CBI).[11] In fact, the NAS committee itself complained that it was denied access to information it needed to conduct its review. In December 2005, USDA's Inspector General (IG) issued a scathing audit, citing APHIS for failure to track GM crop field trials (including ignorance of many field trial locations!), failure to demand written protocols from field trial operators, and numerous missed inspections of field trial sites. APHIS has refused to (fully) implement nine of the IG's 28 recommendations.[12] APHIS itself admits 115 compliance infractions by field trial operators from 1990 to 2001.[13]

APHIS also clears GM crops for commercial cultivation through issuance of a "determination of nonregulated status." As of this writing, 71 petitions for nonregulated status have been approved, involving 14 crops with one or more of seven basic traits.[14] USDA requires considerably more data for deregulation than for field trials, but deregulation is absolute, completely removing the crop and all its progeny from the USDA's regulatory authority. Under the PPA, the USDA is supposed

to deregulate GM crops only if they do not pose "plant pest" or "noxious weed" risks. However, in 1998, the agency approved herbicide-tolerant rice that experts expect will pass this trait to weedy red rice, among rice farmers' worst enemies, making it still more difficult to control. (Canada's Royal Society has described weedy volunteer canola resistant to one, two, and even three herbicides from the crossing of different HT varieties as "a major weed problem" in some parts of Canada.) In addition, APHIS continues to deregulate Monsanto's Roundup Ready, or glyphosate-tolerant, crops (most recently, alfalfa) without considering their tendency to increase the prevalence of glyphosate-resistant weeds by encouraging greater and more frequent use of this herbicide.

EPA

The EPA's primary role is regulation of the plant-incorporated pesticides (PIPs) in crops such as genetically modified *Bt* corn and cotton. *Bt* crops are engineered to produce an insecticidal protein derived from the soil bacterium *Bacillus thuringiensis*. EPA registers these PIPs under FIFRA, while it has the power to set maximum allowable levels (tolerances) of PIPs under the FDCA. EPA has exempted PIPs from tolerances in all currently approved Bt crops. In line with its ruling statutes, which were formulated for chemicals rather than living organisms, the EPA explicitly disavows authority over any aspects of the GM plant beyond its incorporated pesticide. This includes any potentially harmful effects from the genetic engineering process, which are supposedly regulated by the FDA.[15]

While EPA has implemented regulations for PIPs,[16] it has failed to establish data requirements for human safety testing, and instead refers developers of GM pesticide-producing crops to a nearly decade-old guidance (see last endnote) that devotes just four short, inadequate paragraphs to the topic. Although EPA has convened several Scientific Advisory Panels to advise it on GM crop issues, it frequently fails to follow their recommendations.

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And while EPA requires companies seeking approval of pesticide-producing crops to submit various studies, the quality of such studies, and the EPA's review of them, is often questionable. For example, EPA accepted a Monsanto study intended to detect potential effects of a GM pesticidal crop protein on honeybees, despite the fact that the experiment was aborted after nine of the planned 30 days and thus could not give meaningful results. EPA seldom refers to the published, peer-reviewed scientific literature, basing its decisions (especially with respect to potential human health impacts) almost completely on unpublished, corporate studies, which are often deficient.

EPA plays a critical role in the introduction of herbicide-tolerant plants by raising or establishing tolerance levels for herbicide residues on crops. For instance, in 1992 Monsanto successfully petitioned the EPA to more than triple the tolerance for glyphosate residues on soybeans from 6 to 20 ppm. This anticipated the introduction, several years later, of glyphosate-tolerant soybeans. In 2003, the EPA granted a petition from Bayer CropScience to establish a new tolerance for the herbicide glufosinate on glufosinate-tolerant rice.

FDA

The U.S. regulatory agency most commonly cited as vouching for the safety of GM foods exercises the least authority in regulating them. Theoretically, the novel transgenic proteins in GM crops fall under the "food additives" provisions of the FDCA. Food additives must undergo extensive premarket safety testing, including long-term animal studies, unless they are deemed "generally recognized as safe" (GRAS). Biotech companies have successfully claimed GRAS status for all of their new GM proteins (and by extension, the GM crops that contain them). FDA has yet to revoke an industry GRAS determination and require food additive testing of any transgenic crop.

This blanket GRAS exemption is based on the notion of "substantial equivalence"—the strong, *a priori* presumption that GM crops are essentially the same as their conventional counterparts. Interestingly, this policy allowing industry to police itself was established in the face of considerable opposition from FDA working scientists.[17] Some called for mandatory review of every new GM crop; others for toxicology

studies. Dr. Louis Pribyl, an FDA scientist, was particularly concerned about unintended effects from the haphazard introduction of foreign genetic material. Administrative superiors at FDA and the White House apparently did not heed these concerns, resulting in today's voluntary consultation process.

Under voluntary consultation, the GM crop developer is encouraged, but not required, to consult with FDA. The company submits to FDA the conclusions of any research it may have conducted, but not complete studies. FDA never sees the methodological details of the company's research, which is essential to identify unintentional mistakes, errors in data interpretation, or intentional deception. Even within this lax, voluntary system, companies have sometimes failed to comply with FDA's occasional requests for additional data.[18]

Contrary to popular belief, then, FDA has not formally approved a single GM crop as safe for human consumption. Instead, at the end of the consultation, FDA merely issues a short note summarizing the review process and a letter that conveys the crop developer's assurances that the GM crop is substantially equivalent to its conventional counterpart.[19] Under this voluntary system, FDA cannot fulfill its role of reviewing GM foods for the presence of toxins or allergens, alterations in nutritional content, or unintended effects of genetic engineering.[20]

Conclusion

The extraordinary influence of the biotechnology industry has made U.S. regulation of GM crops largely a rubber-stamp process designed to increase public confidence in, rather than ensure the safety of, genetically modified foods. Weaknesses shared by all three agencies include uncritical reliance on the data and conclusions of the financially interested GM crop developer in regulatory decisionmaking; dogmatic adherence to politically-motivated doctrines such as "substantial equivalence" designed to ease companies' regulatory path to approval; and blindness to the substantial economic harm suffered by U.S. farmers thanks to governmental and industry negligence. As continuing contamination episodes provoke more scientifically-oriented regulators in Europe and Japan to reject shipments of U.S. foodstuffs with untested GM content, one can only hope that the often severe economic fallout for U.S. farmers (if nothing else) will convince U.S. regulators to leave politics behind, and finally adopt a more objective, stringent, and science-based regulatory system. ⚠

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1 R. Weiss, *Gene-Altered Profit-Killer,* Wash. Post, (9/21/06). http://www.washingtonpost.com/wp-dyn/content/article/2006/09/20/AR2006092001903.html. R. Weiss, *Biotech Rice Saga Yields Bushel of Questions for Feds,* Wash. Post, (11/6/06). *See also* press releases at http://www.centerforfoodsafety.org/press_room.cfm.

2 Such "herbicide-tolerant" plants comprise fully 82 percent of world GM crop acreage.

3 This is rapidly becoming a multi-million acre and dollar problem with industry leader Monsanto's ubiquitous Roundup Ready crops, engineered for resistance to the company's Roundup (glyphosate) herbicide. For a 2004 overview of glyphosate-resistant weeds, *see* http://ipcm.wisc.edu/wcm/pdfs/2004/04-28weeds2.html. For the latest, *see*: http://www.weedscience.org/Summary/UspeciesMOA.asp?lstMOAID=12.

4 A. Wilson, et al (2004). Genome scrambling: Myth or Reality? EcoNexus Technical Report. http://www.econexus.info/pdf/ENx-Genome-Scrambling-Summary.pdf.

5 Freese & Schubert (2004). *Safety Testing and Regulation of Genetically Engineered Foods,* Biotechnology and Genetic Engineering Review, (Nov. 2004), pp. 299-324. This paper also contains a fuller review of U.S. regulation, complete with references. http://www.foe.org/camps/comm/safefood/gefood/testingregbackgrounder.pdf.

6 K. Eichenwald, G. Kolata, & M. Petersen, (2001). *Biotechnology Food: From the Lab to a Debacle,* NY Times, (Jan. 25, 2001), pp. A1, C6-C7.

7 The regulations governing GM crops were written under the Federal Plant Pest Act, which was subsumed in 2000 (along with several other laws) under the new PPA.

8 R. Caplan, (2005) *Raising Risk: Field Testing of Genetically Engineered Crops in the United States,* US PIRG Education Fund, http://www.uspirg.org/home/reports/report-archives/more-reports/more-reports/raising-risk--field-testing-of-genetically-engineered-crops-in-the-united-states#Rw8Cn4nK-FfjbZ2vdD7-Ew.

9 *See* http://www.isb.vt.edu/cfdocs/fieldtests1.cfm for USDA's searchable database of GM crop field trials.

10 For a partial list, *see* http://www.centerforfoodsafety.org/pubs/Contamination%20episodes%20fact%20sheet.pdf.

11 *Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation*. Committee on Environmental Impacts associated with Commercialization of Transgenic Plants, National Research Council, National Academy of Sciences, Wash., DC: National Academy Press. http://books.nap.edu/catalog/10258.html.

12 *See* http://www.thecampaign.org/USDA_IG_1205.pdf.

13 *See* http://www.aphis.usda.gov/brs/compliance9.html.

14 Compiled from http://www.aphis.usda.gov/brs/not_reg.html. Note that only 4 of these crops (soybeans, corn, cotton, and canola) with one or both of two traits (herbicide-tolerance and insect resistance) account for virtually 100 percent of world acreage actually planted to GM crops.

15 EPA Statement of Policy (1994). Proposed Policy; Plant-Pesticides Subject to the FIFRA and the FDCA, *Federal Register*, Vol. 59, No. 225, (Nov. 23, 1994). http://www.pestlaw.com/x/fedreg/1994/EPA-19941123A.html.

16 EPA PIP (2001). Regulations under the FIFRA for Plant-Incorporated Protectants (Formerly Plant-Pesticides). *Federal Register*, Vol. 66, No. 139, (July 19, 2001), 37771 – 37817. http://www.epa.gov/scipoly/pips.htm.

17 *See* http://www.bio-integrity.org/list.html for internal memos of FDA scientists concerning a draft of what eventually became FDA's 1992 policy on GM foods testing.

18 D. Gurian-Sherman, (2003). *Holes in the Biotech Safety Net: FDA Policy Does Not Assure the Safety of Genetically Engineered Foods*, Center for Science in the Public Interest, (Jan. 2003), pp. 4-5. http://www.cspinet.org/new/pdf/fda_report__final.pdf.

19 *See* Letter for BNF No. 34 at http://www.cfsan.fda.gov/~lrd/biocon.html for Monsanto's MON810 Bt corn, which is typical: "Based on the safety and nutritional assessment you have conducted, it is our understanding that Monsanto has concluded that corn products derived from this new variety are not materially different in composition, safety, and other relevant parameters from corn currently on the market, and that the genetically modified corn does not raise issues that would require premarket review or approval by FDA. … as you are aware, it is Monsanto's responsibility to ensure that foods marketed by the firm are safe, wholesome and in compliance with all applicable legal and regulatory requirements."

20 *See* Freese and Schubert (2004) for examples.