Briefing Paper

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How the US Government is Planning to Approve Contamination of the World's Food Supply with Experimental GM Crops

Overview

Over the past two decades, the United States government has done everything possible to promote its biotechnology industry and push genetically modified (GM) foods on the rest of the world. As part of these efforts, in 2002 the Bush Administration issued a directive that would make contamination of the food supply with unapproved, experimental GM crops "acceptable." This directive is now in the process of being implemented by the US Department of Agriculture (USDA), the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA). Though presented as a food safety measure, the true intent of the policy is to defuse concern over experimental GM traits that escape test plots and contaminate the food and seed supply.

Biotech and food processing companies believe this policy will free them from legal liability for such contamination in the US, and they are already urging the Bush Administration to push the rest of the world to adopt similar policies. In a related move, the head of the FDA recently announced that the agency is considering plans to approve contamination of food crops with drug residues from pharmaceutical-producing crops. Thus, experimental genetic material and pharmaceuticals could enter the world's food and seed supplies from the US, with unknown health and environmental consequences.

Experimental GM Crops: From Lab to Field

All GM crops begin life in the laboratory. Scientists use a "gene gun" or an infectious bacterium to introduce foreign genes encoding the desired trait(s) into clumps of plant cells. Because genetic modification is a random, hit-or-miss process that scrambles plant DNA,[1] most of these lab experiments are failures. GM plants grown from these modified plant cells often have obvious deformities and are weeded out. But those with more subtle problems are frequently missed, and can end up in the fields for outdoor testing, or even be approved for commercial use.[2] Field tests can be fractions to several thousands of hectares, and commonly go on for 5 to 10 years. These field tests thus offer ample opportunity for experimental GM pollen and seeds to contaminate normal crops.

Contamination from Experimental GM Crops

The growing list of GM contamination incidents shows that this is more than a theoretical concern. To give just a few of many examples (see Appendix 1 for more):

- In 2000, nearly 25,000 acres of European rapeseed (canola) and maize were discovered to be contaminated with unapproved GM varieties.
- In 2001, a food aid shipment to Bolivia that originated in the US was found to contain GM corn, despite the country's moratorium on GMOs. In 2002, Bolivians discovered unapproved StarLink in another US food aid shipment. When informed about the StarLink contamination, US authorities did nothing. .

- In 2002, GM pharmaceutical maize produced by ProdiGene, Inc. contaminated maize and soybean fields in Iowa and Nebraska. As a result, 155 acres of maize and $3 million worth of soybeans had to be destroyed.

Contamination with pharmaceuticals from GM crops was reported as early as the year 2000 by Chris Webster of the pharmaceutical giant Pfizer, who stated::

> "We've seen it on the vaccine side where modified live seeds have wandered off and have appeared in other products."[3]

Potential Human Health and Environmental Impacts

All GM crops are subject to potentially hazardous ***unintended*** effects that are impossible to predict and extremely difficult to test for.[4] However, some of these crops are ***intended*** to produce substances that raise human health concerns. The following examples are drawn from the USDA's database of GM crop field trials.[5]

Allergenicity: Tomatoes, potatoes, rice, grapes, wheat and barley have been engineered to produce anti-fungal compounds from the class of pathogenesis-related (PR) proteins, which is "widely regarded as a rich source of allergens."[6] An expert in this field warns that such GM plants could cause food allergies.[7] In addition, many crops are being engineered with an insecticidal toxin derived from a soil bacterium (*Bt*) that might also cause food allergies.

Nutritional deficits: Corn and soybeans are being genetically manipulated for radical alterations in oil, protein and starch content for use as animal feed in factory-farm livestock operations. Manipulating plant metabolic pathways could easily have harmful, but difficult to detect, side effects; and it is far from clear whether such animal feed is suitable for human consumption.[8]

Toxins & sterile plants: Corn, rice, rapeseed (canola) and other crops have been engineered to have sterile pollen or seeds, or "altered fertility." One mechanism for pollen sterility involves generation of barnase, an RNA-degrading enzyme with demonstrated toxicity to rats.[9]

Pharmaceutical crops:[10]

- **GM maize and tobacco** modified to produce aprotinin, which is in a family of compounds known to cause pancreatic disease when fed to animals and is also toxic to honeybees; the aprotinin gene is inserted into tobacco by means of a GM virus that could also infect food crops like tomatoes, potatoes and peppers;
- **GM maize** modified to generate avidin, which kills insects and causes Vitamin B deficiency in mammals, including humans;
- **GM rice** modified to contain synthetic human milk proteins which pose a number of potential human health and environmental hazards;
- **GM tobacco** engineered to produce potent human hormones

Sowing Secrecy

We have listed a few of the known experimental GM crops above. However, most of the "transgenes" introduced into GM plants undergoing field tests are kept secret from the public as "confidential business information" (CBI) of the crop developer. The percentage of field tests with CBI has been climbing steadily since field trials began, from 0% in 1987 to 69% in 2002 (see Appendix 2). Thus, while US government data reveal approximately 500 different transgenes,[11] the true total is probably much higher. We have no way of knowing whether these undisclosed GM crops pose health or environmental risks.

US Regulation of Experimental GM Crops

Since 1987, GM crop field tests have been authorized at more than 40,000 sites, spanning over 200,000 hectares, in the US.[12] Given the likelihood that these experimental GM crops will contaminate food and seed stocks, and considering their potential human health and environmental impacts, one would expect these field trials to be strictly regulated. However, this is not the case. Experimental GM crops undergo no mandatory human health or environmental testing before outdoor planting, and the field trials are virtually unregulated.

Before growing an experimental GM crop, all a company needs to do is submit a 2-page "notification letter" to the U.S. Dept. of Agriculture (USDA) with basic information about the crop, the genetic modification process, and the size and location(s) of the field test.[13] The USDA normally responds with an "acknowledgement" within 30 days. Trials involving plants modified to produce pharmaceutical and industrial compounds are subject to somewhat stricter requirements.[14] Only 3.5% of all petitions to conduct field trials have been turned down.[15] As of 2002, only 10% of "notification" field trial sites had been inspected even once by government regulators,[16] though since 2003 pharmaceutical crop field trial sites are required to be inspected several times.

In no case, however, does the USDA test for contamination of neighboring fields with the experimental GM trait. In 2002, a US National Academy of Sciences committee strongly criticized USDA for these and other regulatory lapses, resulting in minor improvements in USDA's regulatory performance.[17] The FDA does not regulate GM crop field tests.

"Acceptable" Contamination from GM Experiments

On August 2, 2002, a White House directive was issued by its Office of Science and Technology Policy (OSTP).[18] Although the directive has been presented as an initiative to reduce contamination from GM field tests and increase food safety, it is clear that the true intent is to allow routine contamination from GM test sites. The directive states:

> "...intermittent, low levels of biotechnology-derived genes and gene products [in conventional crops or seeds] from such field tests could be *found acceptable* based on data and information indicating the newly introduced traits and proteins meet the applicable regulatory standards." (emphasis added)

OSTP instructed the USDA, the FDA and the EPA to develop procedures by which newly introduced GM traits and proteins in experimental crops could be "found acceptable" as contaminants in the food supply.

USDA: Unlimited Contamination?

The USDA took the first step towards implementing OSTP's directive in January 2004.[19] It sought public comment on the conditions under which it should approve "intermittent and low-level" contamination, which it calls "adventitious presence." However, the USDA did not define what it meant by low-level (e.g. 0.1%, 1%, 10%?) or intermittent (e.g. once a day, once a month or once a year?) contamination, nor is it likely to do so. In a meeting which Friends of the Earth attended, one USDA representative suggested that the government would likely not set any maximum level of permissible contamination (i.e. a tolerance). Instead, enforcement action would be taken only if the GM field trial operator was caught violating the conditions of its field trial authorization.

The USDA has no plans to develop, or require the GM crop developer to provide, appropriate tests for GM contamination from experimental crops. Without such testing, the level and frequency of experimental GM contamination that the US government is proposing to "find acceptable" would not be subject to measurement and so could be unlimited.

FDA: Rubber-Stamping Safety

The FDA released its draft guidance to implement OSTP's directive on November 19, 2004.[20] The proposal sets guidelines allowing companies to voluntarily consult with the FDA on the potential human health impacts of new GM proteins that escape test plots and enter the food supply. This policy is inadequate for several reasons:

- Like all FDA regulation of GM foods, it is voluntary rather than mandatory. Companies are not required to consult with the FDA at all.
- The safety assessment is limited to GM crops producing novel proteins, thus it does not apply to GM crops with metabolic alterations (e.g. for altered oil content or gene silencing) that do not generate novel proteins.
- The policy does not call for any animal tests or advanced analytical techniques to detect unintended effects of the contaminating GM trait, such as unexpected elevations in the levels of native allergen or toxins, or lowered levels of key nutrients.
- FDA only requests two simple tests to indicate whether the novel GM protein is likely to be an allergen or toxin, and fails to even specify how such tests are to be conducted. Experience shows that companies choose test conditions to get the results they want, conditions that can deviate greatly from internationally accepted test protocols.[21]
- Like USDA, FDA sets no limit for the amount of GM contaminant allowed in foods, but merely assumes it will be low.

Clearly, FDA's policy will do little or nothing to enhance food safety. In a recent speech, [22] Lester Crawford, acting Commissioner of the FDA, suggested other purposes for the new guidance:

> "The development of this guidance is a high priority for the Administration and the industry, to ***enhance public confidence, avoid product recalls, and provide an international model*** to address the presence of low levels of bioengineered plant material in non-bioengineered crop fields." (emphasis added)

Crawford then went on to state that

> "FDA has sole responsibility for ensuring the safety and efficacy of the pharmaceutical products produced by plants for use in humans ....Currently, FDA is considering an adventitious presence guidance document analogous to that for food-use crops."

This suggests that the FDA may soon allow contamination of the food chain with residues from GM pharmaceutical crops as well.

EPA: Pesticidal Crops and Temporary Tolerances

The EPA, which regulates GM compounds that act as pesticides in crops, has yet to issue its proposal to implement OSTP's directive. But the directive spells out several features it will have. In particular, the EPA could issue rules to allow GM contamination in food "only as long as necessary to allow any food that might contain residues to pass through the food distribution chain."[23] In other words, if an experimental GM pesticide-producing crop contaminated the food supply, EPA would temporarily approve the contaminant as "safe" for just the period it takes to pass through the food supply, at which point it would presumably become unapproved and potentially unsafe. Clearly, there is no scientific justification for such a "temporary tolerance." It makes sense only as a legalistic contrivance to shield biotech and food companies from liability for contamination of foods with experimental GM pesticidal proteins.

Why is This Happening?

The roots of this contamination approval policy can be traced back to September 2000, when food products in the US were discovered to be contaminated with StarLink, a variety of GM corn unapproved for human consumption. The contamination triggered massive food recalls and lawsuits that in the end cost the biotech and food industries an estimated $1 billion in damages.[24] In July 2001, the EPA rejected a petition from Aventis CropScience (StarLink's developer) to establish a tolerance (i.e. maximum allowable level) for StarLink in the food supply, thereby endorsing a "zero tolerance" policy for unapproved GM traits in food.[25] Aventis had sought this tolerance to avoid liability for recalls and potential health impacts from consumption of StarLink-contaminated products. Years after it was banned, StarLink has continued to show up in US maize as well as food shipments to Bolivia, Japan and South Korea.

Like StarLink, experimental GM crops are not intended for human consumption, pose potential health and environmental risks, and could be considered adulterants if even small amounts get into food or grain. The biotechnology and grain industries believe that establishment of this policy will help shield them from potential liability in the event of a StarLink-like contamination episode involving experimental GM crops in the food supply.[26]

Is Zero Tolerance Necessary?

Friends of the Earth supports a zero-tolerance policy for unapproved, experimental GM crops in the food, feed and seed supply because anything less compromises food safety, allows for potential amplification of GM traits, and provides a disincentive to practice strict gene containment.

Food Safety

Experimental GM crops could cause harm even as low-level contaminants in food. For instance, GM StarLink corn was never approved for human consumption due to concerns that its insecticidal protein (Cry9C) might cause allergies. After StarLink contaminated the food supply, expert scientific advisors to the EPA stated that ***there was no minimal level of StarLink's Cry9C insecticidal protein that could be judged safe for human consumption.***[27] Thus, zero tolerance was the only acceptable standard to protect human health. Several pharmaceutical compounds that have been grown in GM plants in the past (e.g. erythropoietin, GM-CSF) affect the immune system at extremely low levels, in some cases billionths of a gram.[28] Neither consumers nor farmers should be exposed to any level of such potent substances.

Possible Amplification of GM Traits

The transgenes responsible for GM traits are not like inert contaminants. They can spread through cross-pollination with related weeds, and persist over time through the sprouting of unharvested GM seeds in subsequent years. The potential for transgenes to spread and persist is enhanced if the associated GM trait offers a survival advantage, such as resistance to an herbicide or pest.[29] Any related weeds or crop plants that pick up the advantageous trait may have increased survival chances, and even surreptitiously pass it back to the food crop. . Thus, a trait that is initially present at low levels could amplify over time, with unpredictable consequences.

Reduced Incentive to Stop Spread of GM Traits

Eliminating the current "zero tolerance" standard for experimental GM traits in food-grade crops will reduce the threat of liability for such contamination, thereby decreasing the incentive for companies conducting field trials to comply with gene containment protocols. The inevitable result will be more, not less, contamination.

What's in the Ground Now?

Experimental GM crops represent a sizeable source of contamination. While we do not know the total acreage of current experimental GM crop plantings due to corporate secrecy, we know that as of September 14, 2004, there were 1,017 permits in effect covering at least 23,000 hectares. These totals exclude 63 permits for which no acreage is cited. Seven permits authorized plantings over 400 hectares, 12 permits were for 200-400 hectares, and 26 permits were 100-200 hectares in size.[30] Clearly, these larger trials in particular will give rise to substantial transgene flow that in at least some cases will result in contamination of commodity and seed crops beyond the "intermittent" and "low-level" presence presumed in OSTP's proposal.

Contaminating the World, Polluting the Source

Since the US is one of the world's major food exporters, contamination here will have a ripple effect around the world. Indeed, unwanted contamination with GM traits has been detected in food shipments from the US to Latin America, Africa and Asia on many occasions since 2000. Food aid originating in the US has been found to contain GM soy or corn in countries such as Ecuador, Colombia, Bolivia, Nicaragua and Guatemala. Food from the US to Thailand and the Phillippines has also tested positive for GMOs. StarLink corn, unapproved for human consumption due to concerns it might cause allergies, has appeared in food shipments to Bolivia, Japan and South Korea years after it was banned. In 2001, wild maize in Mexico was found contaminated with GM material despite a moratorium on growing GM maize since 1998. US efforts to foist surplus GM maize on Zambia and other African countries was denounced by Africans in 2002.[31] These examples clearly show that whatever is released in the US will find its way all over the world.

Even more disturbing is the growing evidence that GM traits have widely contaminated certified seed stocks.[32] This means that farmers will never know for certain if the seeds they buy are free from genetic contamination. And without this knowledge, they will be unable to take measures to prevent further spread of the trait to their own or neighbors' crops.

No Tests for Experimental GMOs

The examples above illustrate the value of tests that are available for the relatively few GM crops on commercial markets. But could a country or a food company or a farmer know if any given US field or food shipment was contaminated with GM material from test crops? In most cases, the answer is no. The reference materials needed by laboratories to identify most experimental GM traits are not in the public domain (see preceding section and "Sowing Secrecy") And after all, you can only test for something if you know what you are looking for! The end result will be that consumers, farmers and environments worldwide will be unwittingly exposed to GM contamination that in some cases will may well pose human health and environmental risks.

Pushing contamination on the rest of the world

The Biotechnology Industry Organization (BIO) and the U.S. grain industry regard implementation of the White House directive as "enormously important." But they are not satisfied with implementation in the U.S. alone. In an April 2004 joint press release,[33] these powerful trade groups instructed the U.S. government that it "must vigorously promote global adoption of compatible regulatory systems…" as a "key element in a much-needed comprehensive and harmonized ***global approval system*** for regulation of agricultural products of modern biotechnology" (emphasis added). One has to wonder whether such an "approval system" would ever reject a GM crop contaminant as unsafe. This language recalls the comment of FDA Commissioner Lester Crawford in the speech cited above, in which he described one purpose of the FDA guidance as providing "***an international model*** to address the presence of low levels of bioengineered plant material in non-

bioengineered crop fields."
Clearly, US government and industry are united in their resolve to have the rest of the world follow their lead. This is because only a "global approval system" on the US model would allow US biotech and food companies to export food products contaminated with experimental, potentially hazardous GM traits without fear of recalls or other liability.

Friends of the Earth makes the following recommendations:

1) The US government should subject all genetically modified crops to a mandatory and rigorous review in accordance with international standards to detect any human health or environmental impacts they may have before any outdoor planting is allowed.

2) The US government should strengthen its regulation of GM crop trials to prevent contamination of neighboring fields with the pertinent GM trait. To this end, the government should acquire the means to test for such contamination, conduct regular testing, and improve compliance with gene containment protocols.

3) The US government is urged to establish clear rules placing liability for contamination of conventional and organic crops with genetically engineered crop material on the pertinent crop developer.

4) The US government should follow the lead of European countries, Japan, South Korea, and many other nations in establishing mandatory labeling of food products for ingredients derived from genetically engineered plants.

5) We urge the US government to stop pressuring the European Union and other countries to accept genetically modified foods.

The FDA has allowed a period of 60 days from the 25th of November for responses to its proposals. Friends of the Earth urges all concerned citizens, companies and government authorities around the world to make objections to the US government, in the strongest possible terms, against this attempt to contaminate the world's food supplies with experimental GMOs.

The official address for objections is
Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, United States.
Objections can be submitted electronically via //www.fda.gov/dockets/ecomments.
We suggest that all objections are also copied to attention of the Acting Commissioner of Food and Drugs, Lester M Crawford.

APPENDIX 1

TRANSGENIC CONTAMINATION EPISODES[1]

The following are just a few of the dozens of incidents in which contamination from GM crops caused seed or product recalls, and/or other problems for farmers and consumers.[34]

May 1997 — Monsanto is forced to recall 60,000 bags of canola seed when it discovers the seed contains unapproved gene-altered DNA, due to contamination from a planting error by a seed producer.

December 1997 — Unapproved GMO sugar beet from a Monsanto test field is sent to a sugar refiner, where it contaminates natural sugar sold for animal feed.

September 2000 — Over 300 food products were recalled due to contamination by a GMO corn (StarLink, produced by Aventis CropScience), not approved for human food. Experts estimated that half of the state's corn – about 1 billion bushels – could be contaminated. Exports of corn to Japan decreased by 44% in one year. StarLink contamination is still being discovered in US corn shipments three years later.

May 2000 — Nearly 15,000 acres of farmland in five European countries are contaminated with unapproved GMO canola when pollen from the unapproved variety blows into a non-GMO seed producers' field. In addition, French authorities reveal that unapproved GMO seeds have contaminated nearly 10,000 acres of corn planted there.

April 2001 — Just months after the StarLink fiasco, Monsanto is forced to recall thousands of bags of canola seed contaminated with a GMO variety not approved for sale to Canada's major export markets. Incineration is planned for over 10,000 acres of fields already planted with the unapproved crop.

July 2001 – Austrian authorities order thousands of acres of corn destroyed when tests show contamination of non-GMO seed by two unapproved GMO corn varieties.

Sept 2001 – Scientists were surprised to discover GM crop material in wild maize in Oaxaca, Mexico despite the country's moratorium on GM crop cultivation, in effect since 1998. It is thought that GM maize seed in food aid shipments from the US was saved and planted.

April 2002 — Corn grown in Argentina and sold as corn flour in Europe is discovered contaminated with a GMO variety that is not approved for planting in Argentina or for human consumption in Europe.

September 2002 — A pharmaceutical corn, produced by ProdiGene, contaminates corn and soybean fields in Iowa and Nebraska. 155 acres of corn is destroyed and $3 million worth of soybeans are quarantined at the elevator and destroyed.

April 2002 — Corn grown in Argentina and sold as corn flour in Europe is discovered contaminated with a GE variety that is not approved for planting in Argentina or for human consumption in Europe.

May 2003 — Tests show that biotech crops have contaminated wheat grown in the US, even though GMO wheat is not approved for marketing. Grain industry experts warn that approving GMO wheat could mean the end of US exports to Europe and Asia.

July 2003 — Over 100 farmers in Italy discover that the non-GMO corn seed they planted was contaminated with an unapproved GMO variety.

December 2003 — UC Davis researchers discover that, for seven years, they had been mistakenly distributing for research purposes GMO tomato seed in place of a conventional variety.

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1 Based on: BRIEFING ON THE PROPOSED PROTOCOL FOR PHARMACEUTICAL RICE, Attachment 2, Submitted to the AB2622 Advisory Board of the California Rice Commission, March 5, 2004, Prepared by Californians for GE-Free Agriculture

Appendix 2

Percentage of GM Crop Field Trial Authorizations Containing Genes Listed as Confidential Business Information (CBI): 1987-2002[2]

Year	Total No. of Permits	No. Permits with CBI	% Permits with CBI
1987	9	0	0%
1988	18	0	0%
1989	38	0	0%
1990	58	7	12%
1991	107	16	15%
1992	150	49	33%
1993	306	133	43%
1994	593	222	37%
1995	681	250	37%
1996	626	250	40%
1997	744	387	52%
1998	1086	673	62%
1999	986	643	65%
2000	936	621	66%
2001	1121	746	67%
2002	1112	769	69%
Total	8571	4766	56%

2 Based on Appendix G in: CAPLAN, R. (2003). Raising Risk: Field Testing of Genetically Engineered Crops in the United States. *U.S.PIRG Education Fund*, June 2003. http://www.uspirg.org/reports/RaisingRisk2003.pdf

Endnotes:

1 Wilson, A., Lathan, J., Steinbrecher, R. "Genome Scrambling – Myth or Reality? Transformation-Induced Mutations in Transgenic Crop Plants," EcoNexus Technical Report, October 2004. www.exonexus.info.
2 For instance, the paper cited in footnote 1 refers to a variety of transgenic, virus-resistant squash approved by the USDA that has greatly reduced levels of beta-carotene, the substance broken down by the body to form Vitamin A.
3 See "Plant-Derived Biologics Meeting" transcript, April 5 & 6, 2000, p. 77. www.fda.gov/cber/minutes/plnt2040600.pdf
4 For instance, see: KUIPER, H.A.., KLETER, G.A., NOTEBORN, H..P,J.M., KOK, E.J. (2001). Assessment of the food safety issues related to genetically modified foods. *The Plant Journal* **27**(6), Table 6, p. 516.
5 USDA FIELD TRIAL WEBSITE. Information Systems for Biotechnology, Field Test Releases in the US Searchable database of GE crop field trials: http://www.nbiap.vt.edu/cfdocs/fieldtests1.cfm
6 Breiteneder, H. (2004). "Thaumatin-like proteins: a new family of pollen and fruit allergens," editorial, *Allergy* 59(5), p. 479.
7 Hoffmann-Sommergruber, K. (2002). "Pathogenesis-related (PR)-proteins identified as allergens," *Biochemical Society Transactions* (2002), Vol. 30, part 6, p. 934. The anti-fungal compounds referred to include chitinases, thaumatin-like proteins, osmotins and glucanases.
8 Search the USDA database cited above for phenotypes "oil profile altered," "fatty acid metabolism altered," "seed composition altered," "protein altered," and "starch metabolism altered," among others.
9 Search USDA database for "male sterility," "sterility" and "altered fertility." On barnase, see Freese, W. & Schubert, D. (2004). "Safety Testing and Regulation of Genetically Engineered Foods," *Biotechnology and Genetic Engineering Reviews,* Vol. 21, p. 299-323.
10 On aprotinin and avidin, see Appendices 2 & 3, Freese, B. (2002). "Manufacturing Drugs and Chemicals in Crops: Biopharming Poses New Threats to Consumers, Farmers, Food Companies and the Environment," July 2002, Friends of the Earth, www.foe.org/biopharm. On pharmaceutical rice, see: Freese et al (2004). "Pharmaceutical Rice in California: Potential Risks to Consumers, the Environment and the California Rice Industry," http://www.centerforfoodsafety.org/pubs/CARiceReport7.2004.pdf. On hormones, search USDA database under "Gene" for "insulin-like growth factor" and "interferon." For aprotinin in tobacco, search on "TMV" under "Organism"
11 Go to the USDA database at http://www.nbiap.vt.edu/cfdocs/fieldtests1.cfm and select "Gene"
12 Caplan, R. (2003). Raising Risk: Field Testing of Genetically Engineered Crops in the United States. *U.S.PIRG Education Fund*, June 2003. http://www.uspirg.org/reports/RaisingRisk2003.pdf
13 For a "Sample Release Notification Letter," see http://www.aphis.usda.gov/brs/relnot.html.
14 For more on USDA's regulation, see: http://www.aphis.usda.gov/brs/regulatory_activities.html.
15 Caplan, R (2003), op. cit., p. 2
16 Personal communication, James White, APHIS, USDA, on August 2, 2002.
17 *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, Washington, DC: National Academy Press. http://books.nap.edu/catalog/10258.html
18 OSTP (2002). "Proposed federal actions to update field test requirements for biotechnology derived plants and to establish early food safety assessments for new proteins produced by such plants," Notice, Office of Science and Technology Policy, *Federal Register*, Vol. 67, No. 149, p. 50578-50580.
19 "Environmental Impact Statement; Introduction of Genetically Engineered Organisms," Proposed Rule, APHIS, USDA, *Federal Register*, Vol. 69, No. 15, January 23, 2004.
20 "Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use," Draft Guidance for Industry, http://www.cfsan.fda.gov/~dms/bioprgui.html.
21 See Freese, B. & Schubert, D. (2004), op. cit., pp. 307-308, 310.
22 Lester M. Crawford, Acting Commissioner of the FDA. Speech before The U.S. Vatican Mission's Conference "Feeding A Hungry World: The Moral Imperative Of Biotechnology," September 2004 www.agbioworld.org
23 OSTP (2002), p. 50579.
24 "Tests to detect allergens in altered foods fall short," June 12, 2002 *St. Louis Post-Dispatch*, June 12, 2002.
25 "EPA Rejects biotech corn as human food; federal tests do not eliminate possibility that it could cause allergic reactions, agency told," *Washington Post*, July 28, 2001.
26 "US Grain Industry, BIO Urge US Government to Expedite 'Trace-Amounts' Policy for Biotech Products," press release, Biotechnology Industry Organization & National Grain & Feed Association, and other trade groups, April 7, 2004, www.bio.org/newsroom/newsitem.asp?id=2004_0407_01.
27 "Assessment of Additional Scientific Information Concerning StarLink Corn," FIFRA Scientific Advisory Panel to the EPA, SAP Report No. 2001-09, from meeting on July 17/18, 2001.
28 See Freese, B. (2002), op. cit., section 4.9.
29 "Mindful management of genes that produce industrial biochemicals in plants," presentation of Norman C. Ellstrand, geneticist, U of CA Riverside, at the Pew "Pharming the Field" Conference, Washington, DC, July 17 & 18, 2002.
30 Statistics compiled from USDA's website cited above.
31 "Playing with Hunger: The Reality Behind the Shipment of GMOs as Food Aid," Friends of the Earth International, http://www.foei.org/publications/pdfs/playing_with_hunger2.pdf
32 Mellon, M. & Rissler, J. (2004). "Gone to Seed: Transgenic Contaminants in the Traditional Seed Supply," Union of Concerned Scientists 2004. See: www.ucsusa.org.
33 "US Grain Industry, BIO Urge US Government to Expedite 'Trace-Amounts' Policy for Biotech Products," op. cit.
34 "Briefing on the Proposed Protocol for Pharmaceutical Rice," Attachment 2, submitted to the AB2622 Advisory Board of the California Rice Commission, March 5, 2004, by Californians for GE Free Agriculture.