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County of Santa Cruz

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Genetic Engineering (GE)

A Report from the GE Subcommittee of

The Public Health Commission

May, 2006

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EXECUTIVE SUMMARY

The intent of the Genetic Engineering (GE) Subcommittee of the Public Health Commission is to provide information and recommendations to the Board of Supervisors regarding the issues of growing Genetically Engineered or Genetically Modified (GE or GM) crops in Santa Cruz County.

Although "genetic modification" and "genetic engineering" are sometimes used interchangeably, this task force strictly limited its research and recommendations to genetically engineered (GE) food crops. Genetic engineering refers to only recombinant deoxyribonucleaic acid (rDNA) methods that allow a gene from one species to be inserted, and subsequently expressed, in a food crop or other food product.

Recombinant DNA technology combines genes from different organisms in ways that would not otherwise occur in nature, or through traditional plant breeding. An example of a GE crop currently on the market is a corn variety which contains the pesticide Bacillus thurengiensis (*Bt*). Because the *Bt* toxin is contained in every cell of the plant, pests die when they eat the plant. Current GE research in the pipeline includes the insertion of frog genes into potato plants to make them produce a chemical that protects the GE potato from a broad range of fungal and bacterial infections.[1] Corn plants have also been genetically engineered to produce experimental veterinary vaccines to prevent pig diarrhea and other animal health problems.[2]

The GE Subcommittee focused its research on questions submitted by the Board of Supervisors that can broadly be organized in the following categories:

1. An assessment of the status of Genetic Engineering in Santa Cruz County.

2. An investigation of the federal, state and local laws that exist to regulate Genetic Engineering and the identification of regulatory gaps about which the county should be concerned.

3. An analysis of the health, environmental, economic, and social risks associated with growing GE crops in the county.

4. An assessment of whether the Board of Supervisors should consider adopting a moratorium on the growing of GE crops in the county.

The GE Subcommittee convened as a subcommittee of the Public Health Commission in August 2005 at the request of the Santa Cruz County Board of Supervisors. It is comprised of a diverse group of people, with divergent interests and stakes, all of whom have worked cooperatively in the production of this report. This final report represents the culmination of intensive research and discussion by the Subcommittee, which met once or twice each month over a ten month period.

Each section of this report was written by one or more Subcommittee members. Drafts were then presented to the entire Subcommittee where they were discussed, revised, edited and accepted by the voting members. Two Subcommittee members compiled the accepted reports into a final document and submitted it to the Subcommittee for a final review.

[1] Osusky, M., Osuska, L., Kay, W., Santosh, M. (2005) "Genetic modification of potato against microbial diseases: in vitro and in plant activity of a dermaseptin B1 derivative, MsrA2, *TAG Theoretical and Applied Genetics*, 111, 4: 711-722 (August).
[2] "What is the compliance history with APHIS biotechnology regulations?" www.aphis.usda.org

A minority of voting members developed a letter which was presented to the Subcommittee as a non-negotiable document that did not follow this process of review and acceptance of all voting members. A vote was taken and it was agreed that this letter would not be included in the final report.

A majority of voting members voted to recommend a Precautionary Moratorium to the Santa Cruz County Board of Supervisors. There was unanimous consensus by the voting members on all other aspects of the report including the conditions under which GE crops could be grown in Santa Cruz County.

The Public Health Commission also unanimously voted to accept the report and recommended it for submission to the Santa Cruz County Board of Supervisors.

The detailed research embodied in this report has led the GE Subcommittee to recommend to the Board of Supervisors that it add a section to Chapter 7.30 of the Santa Cruz County Code.[1]

The recommended new section would establish a Precautionary Moratorium prohibiting the growing of GE crops in Santa Cruz County. The Precautionary Moratorium would be lifted when certain common sense measures were put into place to safeguard public and environmental health.

It is the belief of this Subcommittee that it is the responsibility and purview of the State of California to establish regulatory oversight to ensure public and environmental health and safety. In the absence of that oversight, the County of Santa Cruz has the right and responsibility to take action by implementing a Precautionary Moratorium that protects the health of the County and its residents and, in doing so, sends a strong message to the state to follow suit.

Critical issues of concern that have led the GE Subcommittee to recommend the countywide adoption of a Precautionary Moratorium include the following:

- Inadequate regulatory monitoring and oversight of genetically engineered crops at the federal and state level to ensure public health and environmental safety. A recent audit conducted by the USDA's Inspector General, found that the Agency is not living up to its own protocols for GE crop regulation. The report found that the USDA did not know the location of many of the GE test sites being used; some GE test crops, including drug-containing crops, remained in the test fields and contaminated subsequent harvests; and some crops not approved for human consumption have found their way into the food supply.

- Health testing of the effects of exposure to GE organisms is not required by any government agency. The lack of comprehensive safety testing leaves a potentially dangerous scientific void in the knowledge available about the short and long-term health effects of GE foods.

- Farmers and gardeners who choose not to grow GE crops have no legal recourse if contaminated by GE pollen or seeds.

- There is no legal requirement to label GE seeds or rootstock, thus eliminating farmers' or gardeners' choices.

- Adequate safeguards do not exist to prevent GE contamination of non-GE crops, plants, insects, domesticated animals, wildlife and wildlands, that can result from forces of nature and human causes. Once GE pollen is released into the environment there is no ability to reverse the process. The resulting impacts on ecosystems are unknown.

[1] Providing for Notice, Indemnification, and Financial Assurances Regarding the use of Recombinant DNA Technology Within the County of Santa Cruz

The GE Subcommittee recommends that the Precautionary Moratorium prohibiting the planting and production of GE crops in Santa Cruz County will be lifted when the following conditions are met:

The State of California implements and enforces its own regulatory system that addresses the concerns and meets all of the following requirements set forth by Santa Cruz County's GE Subcommittee of the Public Health Commission.

1. Field trials of genetically engineered crops are contained to prevent contamination of organic and non-GE crops and weedy relatives.

2. Growing of genetically engineered pharmaceuticals and industrial compounds shall be done in state or federally licensed medical research institutions, medical laboratories, or medical manufacturing facilities engaged in a licensed medical production, and medical research involving genetically modified organisms provided such activities are conducted under secure, enclosed indoor laboratory conditions, with utmost precautions to prevent release of genetically modified organisms into the outside environment.

3. Liability regulations are promulgated that protect organic and conventional farmers and gardeners from contamination by genetically engineered crops, where the financial costs of contamination are borne by the producer of genetically engineered seeds and, only if negligence is found, by the grower of the genetically engineered crops.

4. GE seeds and root-stock shall be labeled so that farmers and gardeners can choose whether or not they want to grow GE crops.

5. The types and location of the GE crops currently being grown and tested in Santa Cruz County shall be communicated to the Agricultural Commissioner and available to the public upon request.

The accompanying report details the present conditions that motivated the GE Subcommittee to recommend the enactment of a Precautionary Moratorium that prohibits the growing of genetically engineered crops in Santa Cruz County. It also specifies the key conditions that the Subcommittee unanimously agreed must be met before the Precautionary Moratorium can be lifted.

The GE Subcommittee further recognizes the potential medical benefits of genetic engineering and recommends that the Santa Cruz County Board of Supervisors adopt a Precautionary Moratorium that includes provisions to allow medical research, as per the conditions set forth in this report.

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1. GE Subcommittee Recommends a Precautionary Moratorium

The GE Subcommittee recommends that the County Board of Supervisors add a section to Chapter 7.30 of the Santa Cruz County Code that would establish a Precautionary Moratorium prohibiting the growing of GE crops in Santa Cruz County. The recommended Precautionary Moratorium is consistent with Chapter 7.30 (.090), which states that the Chapter will be reviewed annually.

Conditions that Must be Met to Lift the Precautionary Moratorium on GE Crops

The Precautionary Moratorium on the planting and production of GE crops in Santa Cruz County will be lifted when the following conditions are met:

The State of California implements and enforces its own regulatory system that addresses the concerns and meets all of the following requirements set forth by Santa Cruz County's GE Subcommittee of the Public Health Commission.

1. Field trials of genetically engineered crops are contained to prevent contamination of organic and non-GE crops and weedy relatives.

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3. Liability regulations are promulgated that protect organic and conventional farmers and gardeners from contamination by genetically engineered crops, where the financial costs of contamination are borne by the producer of genetically engineered seeds and, only if negligence is found, by the grower of the genetically engineered crops.

4. GE seeds and root-stock shall be labeled so that farmers and gardeners can choose whether or not they want to grow GE crops.

5. The types and location of the GE crops currently being grown and tested in Santa Cruz County shall be communicated to the Agricultural Commissioner and available to the public upon request.

County Counsel's Opinion on the Legality of a Moratorium

Chris Cheleden (Santa Cruz County Counsel's Office) reported to the GE Subcommittee that a few counties in California have considered a GE moratorium or similar measures, either as a Board adopted ordinance or through the initiative process. The county counsels in those counties have analyzed the possibilities for legal challenges to the measures on preemption, constitutional, and other related grounds, which he also reviewed. The results of Mr. Cheleden's research indicate that while there are legal arguments on both sides of the issue, no state or federal case or statutory law has directly addressed the legality of a moratorium. Mr. Cheleden also conducted a search of case law on the national level but did not find any precedent that had ruled on the legality of a GE moratorium at the local level. Additional legal research by County Counsel will be necessary to advise the Santa Cruz Board of Supervisors with respect to the specific proposed Precautionary Moratorium under consideration.

2. Overview of the Regulatory Framework

The Coordinated Framework for Regulation of Biotechnology of 1986 is the regulatory framework for genetically engineered organisms. It is administered by three federal agencies, the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA).

Food and Drug Administration (FDA)

The FDA is responsible for the safety of food and animal feed and for the safety and efficacy of human and animal drugs, biologics and dietary supplements. Genetically engineered plants injected with natural biological materials are not considered "food additives" and thus, no pre-market approval is required.

The FDA's Biotechnology Policy consists of voluntary consultations with biotechnology developers, whereby the developer can submit to FDA a summary of its scientific and regulatory assessment of the food and the FDA evaluates the submission and responds to the developer by letter.

There was a pre-market notification proposed rule[1] that would have required developers to submit a scientific and regulatory assessment of a bioengineered food 120 days before a bioengineered food could be marketed. The comment period for proposal ended on April 3, 2001. To date, the proposal has not been made final.

As a result of the Food Allergen Labeling and Consumer Protection Act of 2004, effective January 1, 2006, FDA requires food products that contain any ingredients containing protein derived from the eight major allergenic foods to be clearly labeled. Thus, genetically engineered plants containing such allergenic proteins are required to be clearly labeled as potential allergens. However, there is no requirement that food be labeled as genetically engineered.

United States Environmental Protection Agency (EPA)

The EPA is responsible for regulating pesticides under the Federal Insecticide, Fungicide and Rodenticide Act. The EPA ensures that pesticides pose no unreasonable risk to the environment and sets allowable levels, or tolerances, or exemptions from tolerances for pesticide residues in food under the Federal Food Drug and Cosmetic Act (FFDCA).

Plant-incorporated protectants (PIPs) are the genetically engineered pesticidal substances produced by plants. (See **Appendix 1**—List of PIPs) They require the same pre-marketing approval as other pesticides. Before the EPA registers a pesticide for use in the market, the EPA requires extensive studies examining risks to human health, non-target organisms and the environment, potential for gene flow and the need for insect resistance management plans. Environmental Use Permits (EUPs) are also required for testing PIPs on a cumulative total of over 10 acres.

There is an exemption from the requirement of a tolerance under the FFDCA for residues of nucleic acids that are part of PIPs, as the EPA believes that exposure to residues of nucleic acids will not cause harm, as nucleic acids are normally a component of food from plants.[2] The exemption does not extend to nucleic acid analogues (e.g., dideoxycytidine), or polymers containing such analogues.

[1] January 18, 2001, 66 FR 4706
[2] July 19, 2001, 66 FR 139

United States Department of Agriculture (USDA)

USDA's Animal and Plant Health Inspection Service (APHIS) is responsible for preventing the importation and interstate dissemination of plant pests and noxious weeds. APHIS's Biotechnology Regulatory Services (BRS) program regulates the field testing, movement, and importation of genetically engineered organisms that are known to be or could be plant pests.

When a GE plant is imported, transported interstate or planted, APHIS requires either notification or an application for a permit. Notification is a streamlined approval process, whereby the developer submits a Release Notification Letter[1] to BRS certifying that the GE plant will be introduced according to the eligibility criteria and performance conditions required to manage the introduced plant so that its offspring will not persist.

Under the notification process, BRS either acknowledges or denies the appropriateness of interstate movement or release of the plant within 10 or 30 days respectively. Permits are more restrictive than notifications, taking up to 120 days to process and requiring scientific review of the performance conditions and a detailed description of the confinement measures.

The notification process originally applied to only six crops, but subsequent revisions to the regulations have extended eligibility to nearly all plants, excluding noxious weeds. According to the Pew Initiative on Food and Biotechnology ("Pew Report") "[n]early 99% of all field tests, importations, and interstate movements of GE plants are performed under the notification process."[2] Microorganisms and pharmaceutical-producing plants require a full APHIS permit.

BRS is charged with compliance of the performance standards for the field tests or release of GE crops, including conducting inspections and audits. According to APHIS, "[d]epending on the GE crop being tested, a site may be inspected by APHIS at least five times during a single growing season to ensure that the conditions set forth by BRS are carefully followed."

However, the USDA's Office of Inspector General issued a recent report finding "that biotechnology regulators did not always notice violations of their own rules, did not inspect planting sites when they should have and did not assure that the genetically engineered crops were destroyed when the field trial was done."[3]

The Office of Inspector General report was the result of an audit conducted from May 2003 to April 2005 and consisted of visits to 91 field test sites and review of records. At eleven of the field test sites the auditors found thirteen instances of violations of rules. According to the report, BRS "lacks basic information about sites it approves and is responsible for monitoring, including where and how the crops are being grown, and what becomes of them at the end of the field test."

In order for a GE plant to become available for general release, the plant must become "deregulated." This is accomplished by petitioning APHIS for non-regulation status, and demonstrating that there will be no significant plant pest risk from widespread planting. APHIS requires an environmental assessment as to whether the proposed plant would have a significant impact on the environment.

If APHIS finds that an action would have no significant impact, it publishes its finding in the *Federal Register* and deregulates the plant. If APHIS cannot make a finding of "no significant impact" then the National Environmental Policy Act requires an Environmental Impact Statement ("EIS"). The April 2004 Pew Report noted that "[t]o date, APHIS has not conducted an EIS for any deregulation petition."

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[1] See sample letter attached in **Appendix 2.**

[2] Issues in the Regulation of Genetically Engineered Plants and Animals", p.21, a report from the Pew Initiative on Food and Biotechnology, *April* 2004

[3] U.S. Department of Agriculture Office of Inspector General Southwest Region Audit Report Animal and Plant Health Inspection Service Controls Over Issuance of Genetically Engineered Organism Release Permits. (www.usda.gov/oig/webdocs/50601-08-TE.pdf).

Once the plant is deregulated APHIS no longer has regulatory authority over the plant because it is not a plant pest, unless APHIS re-regulates the plant. Re-regulation would of course require a showing that the deregulation was an error. APHIS does have the authority to take action if it makes a declaration of extraordinary emergency and pays compensation for economic losses.[1]

Currently, APHIS BRS is preparing a programmatic EIS on the environmental consequences of regulatory changes for the importation, interstate movement and environmental release of GE organisms. After the EIS is prepared, BRS will propose new regulations.

Topics BRS is considering include, enhancing authorities to regulate the full range of GE plants beyond those which can pose plant pest risk, and replacing the current permitting and notification systems with a multi-tiered, risk-based permitting system.[2]

California Department of Food and Agriculture (CDFA)

CDFA reviews and comments on USDA permit applications to bring new GE crops into the state for research purposes. By its own admission, the Agency currently lacks the in-house expertise to perform thorough assessments of proposed GE research projects. In addition, critical information is often classified as confidential and is frequently unavailable to CDFA in its evaluation of possible environmental hazards posed by GE experimentation.

Pre-Market Gaps in Regulatory Oversight

- The laws guiding FDA, USDA, and EPA on GE crops predate the development of GE crops. [3]
- No human safety tests are required by USDA or FDA on GE crops.[4] The only safety requirement is an EIR by EPA for the registration of plant incorporated protectants (PIPs). An EIR has been done on only 17 of all the GE crops approved. According to the FDA, GE foods are to be generally regarded as safe (GRAS), except those containing genes from the ten most allergenic compounds. Therefore, the Agency requires no pre-market safety testing.[5]
- GE manufacturers are not required to provide proof of safety of GE crops. They are asked to do voluntary consultations with the FDA. They are not required to share actual data with the FDA but only summaries of their in-house assessments.[6]
- No labeling of GE seed is required at state or federal level.[7]
- CDFA does not have regulatory authority over GE crops. The agency sometimes acts as a contractor for federal agencies.[8] "None of the employees of CDFA is dedicated full time to crop biotechnology". [9]

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[1] www.ucbiotech.org/resources/

[2] For field test trait, crop, and site lists see: http://aphis.usda.gov and http://www.isb.vt.edu/CFDOCS/fieldtests1.cfm

[3] Rebecca Spector, Center for Food Safety website www.cfs.org, Dec. 2005; Mike Lee and Edie Lau, "Scattered Efforts" from Seeds of Doubt series, Sacramento Bee, June 6-10 2004; Marion Nestle, *Safe Food: Bacteria, Biotechnology and Bioterrorism,* (University of California Press, Los Angeles and Berkley, CA. 2003) p.195

[4] Spector; Martin Teitel Ph.D., and Kimberly A. Wilson, *Genetically Engineered Food: Changing the Nature of Nature*, (Park Street Press, Rochester, VT, 1999), p. 32; "Gaps Analysis report by rBST Review Team Health Protection Branch of Health Canada", April *1998;* Jeffrey Smith, *Seeds of Deception*, (Yes! Books, 2003), p. 30, 84, 85, 143; Nestle p.194; Ronnie Cummins and Ben Lilliston, *Genetically Engineered Food: A Self Defense Guide For Consumers*, (Marlowe and Company, NY, NY, 2000) p.83, 92

[5] Spector; Nestle, p. 208,209

[6] Spector; Lee and Lau; Nestle, p. 209

[7] California Seed Law (from the Food and Agriculture Code)

[8] Spector; Lee and Lau

[9] Lee and Lau

- GE manufacturers are not required by federal agencies to provide key information in applications submitted to CDFA. Things like location, gene trait or variety can be omitted by claiming CBI (confidential business information) and, therefore, not available to the public.[1]

- California has had no EPA inspections between 1987 and 2004 on more than 1100 tests of GE crops.[2]

- Regulatory agencies and GE producers do not always follow protocols, and at times, there is no consequence when those procedures are not followed.[3]

- APHIS (USDA) does not have regulatory authority over a GE plant once it is deregulated.[4]

- Once GE crops are deregulated, no buffers are required between GE crops and non-GE crops and no required public notification of the planting of GE crops.

- Conventional and organic farmers and gardeners have no legal recourse if their crop is contaminated with GE pollen or seed.[5] Non-GE farmers may face lawsuits for patent infringements if they collect GE seeds that migrated onto their field from their neighbors' previous season's planting of GE crops.

- Chapter 7.30 of the Santa Cruz County Code (Providing for Notice, Indemnification, and Financial Assurances Regarding the use of Recombinant DNA Technology within the County of Santa Cruz) does not include notification of GE plantings on city or university land.

Post-Market Gaps in Regulatory Oversight

- No labeling of GE food products is required.[6]

- Once a GE crop is approved, companies may not be legally required to report problems.[7]

- There is no monitoring or testing for imported GE foods.[8]

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[1] Ibid; (confirmed by David Nunencamp of CDFA in a phone conversation with A.Mangan)

[2] Rebecca Spector, Center for Food Safety website www.cfs.org, Dec. 2005; Mike Lee and Edie Lau, "Scattered Efforts" from Seeds of Doubt series, Sacramento Bee, June 6-10 2004; Marion Nestle, *Safe Food: Bacteria, Biotechnology and Bioterrorism,*(University of California Press, Los Angeles and Berkley, CA. 2003) p.195

[3] U.S. Department of Agriculture Office of Inspector General Southwest Region Audit Report Animal and Plant Health Inspection Service Controls Over Issuance of Genetically Engineered Organism Release Permits. www.usda.gov/oig/webdocs/50601-08-TE.pdf

[4] Issues in the Regulation of Genetically Engineered Plants and Animals", p.21, a report from the Pew Initiative on Food and Biotechnology

[5] Lee and Lau; Ronnie Cummins and Ben Lilliston, *Genetically Engineered Food: A Self defense Guide For Consumers*, (Marlowe and Company, NY, NY, 2000) p. 97.

[6] Jeffrey Smith, *Seeds of Deception,* (Yes! Books, 2003), p. 142; Marion Nestle, *Safe Food,* p.194; Cummins and Lilliston, p.97.

[7] Lee and Lau; "Issues in the Regulation of Genetically Engineered Plants and Animals, " p. 21, a report from the Pew Initiative on Food and Biotechnology

[8] Cummins and Lilliston, p.93

3. Tracking and Monitoring of GE Crops

GE Contamination

It is widely recognized by scientists, regulators, and the genetic engineering industry that the migration of genetically engineered organisms beyond their intended destination on the farm is inevitable.[1] This argument is further substantiated by partial list of U.S. contamination incidences presented in **Table 1**.

Insufficient regulation of both GE field trials and deregulated genetically engineered crops enables GE contamination to occur across the agriculture commodity chain, from the seed to the table. This puts consumers at risk of eating genetically engineered food not intended for human consumption and of eating genetically engineered pharmaceuticals and polymers grown in food crops and in open fields.

GE contamination results from a wide range of human and environmental related activities. Once released into the environment, transgenes cannot be recalled and they will be passed on to subsequent generations of plants through natural biological processes, making complete clean up or removal of GE plants virtually impossible.[2].

Environmental sources of contamination include cross-pollination and seed movement by wind, water, insects, wildlife, birds, and domesticated animals. Studies have shown that contamination has also occurred when volunteer GE plants and pharmaceutical crops are left in the field from the previous season's plantings. Human error can also cause GE contamination due to the improper segregation, handling, transfer, transport, and labeling of seeds and seedlings, and the establishment of inadequate and permeable buffer zones.[3].

Also at risk from GE contamination are organic and conventional farmers who rely upon the availability of non-GE seeds and the production of non-GE crops to maintain access to export markets that restrict GE imports. GE contamination threatens organic markets and the price premiums of organic farmers who depend upon the ability to grow crops with non-GE seeds and seedlings. The contamination issue is further complicated by the absence of laws designed to assess liability and assign payments and restitution to farmers contaminated by genetically engineered organisms. (For a more complete discussion, see the **Liability** section of this report.)

Although the USDA's Animal Plant and Health Inspection Services (APHIS) is charged with permitting and monitoring GE field research, recent evidence suggests that the agency is negligent in fulfilling its oversight role. According to the findings of a report released by the USDA's Inspector General in December 2005,[4] APHIS does not follow up with all permit and notification holders to find out exactly where test fields have been planted or if they have been planted at all (p. ii).

The Inspector General's report notes with concern that before approving field tests, APHIS does not review the notification applicant's containment protocols which describe how the applicant plans to prevent the GE from persisting in the environment outside of the field test site (p. ii). APHIS also does not effectively track required field test site information, including the permit holder's progress reports, the results of field tests, and any harmful effects on the environment discovered during the test. (p. ii). Approved applicants sometimes allow harvested crops to lie in the field test site for months, allowing GE test seeds to be scattered by the rain, wind, animals, birds, and insects (p. iv). These are just four

[1] Marvier, Michelle & Rene C. Van Acker (2005) "Can Transgenes be kept on a Leash?" *Front Ecol Environ,* 3, 2: 96-106.
[2] *Ibid.*
[3] Altieri, M. A. (2005) "The Myth of Coexistence: Why Transgenic Crops are not Compatible with Agroecologically Based Systems of Production.", *Bulletin of Science, Technology & Society*, 25, 4: 366.
[4] http://www.usda.gov/oig/webdocs/50601-08-TE.pdf

examples of the many problems noted in the report about the failure of APHIS to adequately monitor and evaluate field tests and prevent GE contamination.

The StarLink contamination case provides the most well-known incident of GE contamination of the food supply.[1] The USEPA did not approve StarLink's GE corn containing the toxin Cry9C for human consumption because of the potential for serious allergic reactions to occur in humans. Although less than 1 percent of the U.S. corn crop planted in 2000 was StarLink, this GE animal feed corn contaminated 22 percent of the grain tested by the USDA.[2] Contamination occurred due to the inadvertent mixing of StarLink with other corn in grain elevators. Some proportion of StarLink corn was found in over 10 million individual food items containing corn, including taco shells sold in Taco Bell fast food chains and other restaurants, and food sold in stores across the country. Unfortunately, a massive product recall came only after this GE corn had been eaten by tens of millions of people. [3]

[1] Hileman, Bette. (2003) "ProdiGene & StarLink Incidents Provide Ammunition to Critics," *Chemical and Engineering News,* 81, 23: 25-33; Goldenberg, Suzanne. (2002) "Alarm as GM pig vaccine taints US crops, Strict new guidelines planned after contamination," *The Guardian,* (December 24).

[2] Smith, Jeffrey M. *Seeds of Deception,* 2003, Fairfax, Iowa: Yes! Books, pp. 167-168.

[3] *Ibid.*

Table 1

(see **Appendix 7** for complete references)

DATE	CONTAMINATION INCIDENT
1. Sept. 2000	Traces of Aventis *Bt* corn (StarLink), not approved for human consumption, are identified in taco shells manufactured by Kraft Foods and distributed through the fast food chain, Taco Bell, and to other restaurants and stores.
2. June 2001	USDA purchases over 322,000 *Bt* Cry9c (StarLink) GE corn seed from small and medium seed companies because the seeds were not approved, or determined safe, for human use. It costs taxpayers nearly $13 billion.
3. Nov. 2002	North Dakota State University Foundation Seedstocks are contaminated with GMOs to the extent that it may be difficult to segregate GM from non-GM wheat seed.
4. 2002	APHIS found volunteer corn crops growing in a soybean field that had been used as a test site for a pig vaccine grown in corn during the previous year.
5. 2002	At a second location, APHIS found volunteer corn (with tassels) from the previous year's field test growing in a soybean field. The GE corn contaminated soybeans were harvested and sent to a grain elevator and mixed with 500,000 bushels of soybeans. APHIS destroyed the soybeans and fined the seed producer, Prodigene, $250,000.
6. Feb. 2003	FDA determined that GE pigs involved in University of Illinois-Urbana/Champaign studies may have entered the food chain after researchers released 386 of the GE experimental pigs to a livestock dealer for slaughter and sale.
7. Dec. 2003	UC Davis recalls 30 tomato seed samples, distributed to research colleague in the US and abroad over a seven year period, when tests showed that the mislabeled samples were GE tomatoes and not the intended non-GE variety.
8. Feb. 2004	Study finds "corn, soybeans and canola are pervasively contaminated with low levels of DNA sequences derived from transgenic varieties."
9. Aug. 2004	Scotts Company of Maryville, Ohio, failed to notify APHIS on two occasions of accidental or unauthorized releases of RoundUp Ready Creeping Bentgrass which occurred when wind spread the GE seed heads beyond the test site location.
10. Sept. 2004	Seminis Vegetable Seeds, Inc. Oxnard, CA shipped GE tomato seeds to UC Davis without proper identification.
11. March 2005	Syngenta sows 150 square kilometers of *Bt* corn, over a four year period, without USDA regulatory approval.
12. May 2005	Unauthorized shipment of GE (*Bt*10) maize-contaminated feed from the US is stopped at Irish port.
13. Aug. 2005	Japan discovers a US feed grain cargo tainted with GE (*Bt*10) corn and orders the importer to destroy the corn or ship it back to the US. It was the ninth discovery and rejection by Japan since testing began in May 2005.

GE Field Tests in Santa Cruz and Surrounding Counties

Field testing of GE crops is conducted by institutions seeking to ascertain market approval for a particular GE crop. Such tests are required by APHIS in order to monitor the expression of a desired trait under experimental conditions.

The permitting process does not involve any public disclosure of an applicant's intent to test a genetic trait or any opportunity for public review or comment on a given permit. Once a field test permit is granted, the permitted institution may conduct field tests at multiple locations and in multiple states within a specific period of time.

The permit applicant is not required to notify the authorities of its intent to test GE crops in the state; however, APHIS is required notify the appropriate state authorities before the final permit approval is made. By law, field tests sizes have no limit and have been documented to vary from a few acres in size to over 1,000 acres. APHIS deregulates a test crop if it determines that enough evidence exists to allow for the deregulation and subsequent commercialization of the crop.[1]

In California, 1,203 field tests have taken place since the inception of the APHIS field test program in 1987 and 2005. (See **Table 2)** Between January 1st and September 28th, 2005, 74 field tests have been conducted across the state at undisclosed locations.[2]

GE traits present in California field trials include: herbicide tolerance (30%), product quality (26%), insect resistance (14%), virus resistance (13%), agronomic properties (9%) and other (8%), fungal resistance (7%), marker gene (5%), bacterial resistance & nematode resistance (1%). (See **Table 3**)

The public is not entitled to readily access information regarding the types, number, size, or location of field tests that are being conducted in the US. The records of such information are maintained by the federal government at various APHIS-related offices throughout the Washington, DC metropolitan area.

There are also some restrictions on the types of information that APHIS will release to the public, particularly if the applicant claims that such information constitutes "confidential business information" (CBI). Although public institutions such as universities tend to allow the public disclosure of test site locations, private research institutions and corporations tend to claim that such information as CBI.[3]

Freedom of Information Act (FOIA) requests, however, can be made to APHIS by a person from the public who would like to know what types of field tests are taking place in her/his community. However, as you will see from the investigation conducted by our GE Subcommittee, such information is not always forthcoming.

[1] http://www.aphis.usda.gov/brs/qarel/htm
[2] http://www.isb.vt.edu/cfdocs/biocharts2.cfm
[3] For field test trait, crop, and site lists see: http://aphis.usda.gov and http://www.isb.vt.edu/CFDOCS/fieldtests1.cfm.

Table 2

GE FIELD TRIALS

CROP	TOTAL		IN EFFECT	
	Number of Issued Permits & Acknowledged Notifications (1203 Total)	Percentage of California's Total GE Field Trials	Number of Issued Permits & Acknowledged Notifications (110) Total	Percentage of California's Total GE Field Trials
Tomato	299	25%	16	15%
Corn	193	16%	38	34%
Cotton	84	7%	6	5%
Rice	82	7%	5	6%
Melon	72	6%	0	0%
Lettuce	61	5%	2	2%
Rapeseed	60	5%	4	4%
Alfalfa	56	4%	16	14%
Potato	40	3%	0	0%
Strawberry	31	3%	0	0%
Beet	27	2%	0	0%
Squash	24	2%	0	0%
Grape	20	2%	8	7%
Wheat	18	2%	0	0%
Walnut	12	1%	1	1%
Sunflower	11	1%	0	0%
Apple	10	1%	0	1%
Pepper	8	1%	0	0%
Tobacco	4	<1%	0	0%
Other	91	8%	13	13%

SOURCE: VIRGINIA TECH UNIVERSITY DATABASE OF USDA/APHIS PERMITS

Excerpted from: Spector, Rebecca, Kimbrell, Andrew, & Morris, Amy Wilson. (January, 2006) *California Food and Agriculture Report Card: Genetic Engineering,* "State of the State," Center for Food Safety, Washington, D.C.

Table 3

GE TRAITS IN CA FIELD TRIALS

TRAIT	TOTAL (1987-2005)		IN EFFECT (Current)	
	Number of Issued Permits/Acknowledged Notifications (1203 Total)	Percentage of California's GE Field Trials	Number of Permits/Notifications in Effect (123) Total	Percentage of California's Current GE Field Trials
Herbicide Tolerant	359	30%	28	23%
Product Quality	311	26%	15	12%
Insect Resistance	167	14%	7	6%
Virus Resistance	158	13%	6	5%
Agronomic Properties	103	9%	30	24%
Other	92	8%	15	12%
Fungal Resistance	83	7%	8	7%
Marker Gene	55	5%	8	7%
Bacterial Resistance	17	1%	5	4%
Nematode Resistance	4	>1%	1	>1%

Excerpted from: Spector, Rebecca, Kimbrell, Andrew, & Morris, Amy Wilson. (January, 2006) *California Food and Agriculture Report Card: Genetic Engineering,* "State of the State," Center for Food Safety, Washington, DC.

FOIA Request for Information about GE Field Tests in Santa Cruz

Between October 3rd and December 15th 2005, a GE Subcommittee member submitted a series of Freedom of Information Act (FOIA) requests to APHIS to determine the types of GE crops and traits that are being field tested in Santa Cruz and the surrounding Counties (See **Appendix 3**).

After speaking with an APHIS representative, it became clear that the likelihood of receiving a timely response from the Agency would substantially increase if the request pertained to a single growing season at a time. Therefore, FOIA requests were made for all documents containing information regarding GE field tests during the years 2004 and 2005 for the following counties: Santa Cruz, Santa Clara, Monterey, San Bonito, San Mateo, Alameda and Kern. We chose to include Kern and Alameda Counties as control sites because we know that GE crops are being grown in Kern County and expect that field tests are being conducted in the County. The other control site, Alameda County, was chosen because we knew that GE research was being conducted at a public research institution in that county at the University of California, Berkeley.

As of mid February 2006, only one out of the seven FOIA requests submitted has been answered and that was in response to our earliest inquiry about Santa Cruz County, dated October 3rd 2005. In a letter dated, November 4th 2005, an APHIS representative stated: "Agency employees conducted a thorough search of their files but were unable to locate any records responsive to your request. They have advised this office that there were no field tests of genetically engineered cops conducted in Santa Cruz County during 2004 or 2005."

We received a standard form letter in response to the remainder of our FOIA requests which explained why APHIS would not be able to answer our request as per the time limit required by law. The response states: "The records you seek are maintained outside of this Office and we have not been able to complete a search to determine whether there are records within the scope of your request. Accordingly, we will be unable to comply with the twenty-working-day time limit in this case, as well as the ten additional days provided by the statute." (See **Appendix 3**) Oddly, this response was dated only five days after the receipt of our request, suggesting that it is standard APHIS policy to ignore compliance with the statutory time limits.

Based upon our research, we do not feel that we have sufficient evidence to draw any concrete conclusions about the status of GE field tests occurring in Santa Cruz and the surrounding counties for several reasons.

First, since we did not receive a response from APHIS regarding the types of GE research conducted in the counties surrounding Santa Cruz, and since GE pollen and seeds are known to travel long distances, there is no way to know whether GE test crops or test organisms are present in Santa Cruz County.

Secondly, a recent internal evaluation of APHIS by the USDA's Inspector General casts doubt on the Agency's ability to adequately track, monitor, and evaluate GE field tests. The report, released in December of 2005, specifically states that "APHIS lacks basic information about the field tests it approves" (p. i)." Such lack of information includes the precise location of the GE field test or "the final disposition of GE pharmaceutical and industrial harvests, which are modified for nonfood purposes and may pose a threat to the food supply if unintentionally released," (p. ii). The Inspector General also found that "APHIS does not "sufficiently document their review process and scientific basis for approving field test applications. APHIS does not effectively track information required during field tests, including approved applicant's progress reports, which should contain the results of field tests, including any harmful effects on the environment," (p. ii).

Given these and other acknowledged shortcomings in the GE field test permitting process, the most we can say is that the occurrence of GE field tests in Santa Cruz County, past or present, remains largely unknown.

4. Economic

California and Local Agricultural Economy: Background

Agricultural production and processing are estimated to account for between 6% and 7% of California's total income (value-added) and jobs.[1] These percentages are estimated to be much higher, between 19% and 25%, in agriculturally productive areas such as the Central Valley. Though the Central Coast and Santa Cruz County are not reported as separate statistics, this county is characterized as agriculturally diverse and productive.

For Santa Cruz County, agriculture is a leading industry, contributing significantly to the overall economy. The gross production value of agricultural commodities in Santa Cruz County in 2004 was $448 million dollars.[2] When one considers the infrastructure and other industries and businesses supported by agriculture, it is clear that any positive or negative impacts to the agricultural industry will affect the county's economy. It has been estimated that gross agricultural dollars can be multiplied by roughly $3 to measure the economic impact of the local industry.[3]

For California, organic agriculture revenue was estimated to be $330 million in 2003, the latest year for which statistics are available.[4] This represents roughly one percent of all agriculture for the state. Fifteen percent of the total acres of fruits and vegetables grown in Santa Cruz County are grown organically.[5] In Santa Cruz County, seventy growers farm roughly 2,700 acres with total organic production estimated at $18 million. This represents roughly four percent of the total value of agricultural production for the county.

In a recent survey commissioned by the Santa Cruz County Farm Bureau, 76% of respondents reported they make an effort to purchase organically grown food.

Present and Potential Status of GE Crops in Santa Cruz

Under current state and federal regulation, there is no way to determine if any deregulated GE crops or seeds are being planted in Santa Cruz County. Only four transgenic crops currently approved of by the federal government are being grown commercially on a large scale (soy, cotton, canola, and corn) and those crops aren't grown here.

There is a potential, over the next few years, that many other transgenic crops will be approved and move into open production. In 1994, 8,700 acres in the U.S. were used to test experimental, genetically engineered or genetically modified crops. By 2004, this number rose to 67,000 acres.

Of the thirty-nine commercial crops grown in our county, eighteen crops had gross production values in 2004 ranging from $1,462,000 to $194,755,000. GMO or GE research is currently being done on eight of these top value Santa Cruz crops, with California field trials being done on five of them. In all, the biotechnology industry is conducting case studies, research or field-tests on twenty-seven of our thirty-nine commercial crops (See complete list in **Appendix 4**). Therefore, the potential exists for GE crops to be grown in Santa Cruz.

[1] Kuminoff, Sumner and Goldman. 2000. UC Agricultural Issues Center. http://aic.ucdavis.edu/pubs/moca.html
[2] Santa Cruz County Agricultural 2004 Crop Report http://www.agdept.com/content/cropreport_04.pdf)
[3] Richard Nutter, subcommittee member and Dave Moeller, Santa Cruz County Agricultural Commissioner
[4] Klonsky and Richter. 2005. UC Agricultural Issues Center. http://www.aic.ucdavis.edu/research/StatisticalReview98-03f8.pdf
[5] Santa Cruz County Agricultural Commissioner. 2004. Crop Report

Labeling and Trade Issues

There are currently no labeling regulations in the U.S. for deregulated 'first generation' GE field crops. It is not known at this time if 'future generation' GE crops, horticultural or pharmaceutical, will have any labeling requirements.

If labeling were to be required for market acceptability or regulatory reasons, costs to producers, industry, and consumers would be incurred. Specific costs are unknown at this time but research suggests that the greater the level of documentation, labeling, and potential for associated liability claims within the food system, the greater the cost will be. These costs will be absorbed somewhere along supply chains and/or the total food system.[1]

Several countries require labeling for GE products, including Australia, New Zealand, and all of the European Union, Japan and Korea require labeling for certain GE agricultural products. Other countries in Asia and Latin American have initiated efforts to implement labeling regulations. Some Latin American and African nations have developed, or are in the process of developing, bio-safety policies and laws.[2]

Swiss voters recently approved a referendum (November 2005) for a five-year moratorium on genetically modified animals and crops except for use in research to produce medicine. (See **Appendix 5 -** Other Countries' Requirements for GE crops).

Impacts Common to Both Conventional (Non-GM) and Organic Production

There are many potential sources of genetic contamination on conventional and organic crops by GE organisms. This makes it essential to consider the question of liability for resulting market losses that can arise from contamination (see **Liability** section of report). There is a potential for loss of market price for both conventional (non GE) and organic growers.

Buyers and processors who suffer economically losses may attempt to recover those costs from the farmers. The farmer has lost a sale and, even if he was not negligent, he may still be found in violation of a contract or foreign statute.

An organic grower could face a loss of certification for the acreage and liability issues to a landlord (if the land was leased) and additional costs to amend and have the acreage re-certified. Organic certification is generally a minimum three-year process so an organic farmer would also lose income during a re-certification process.[3]

We do not know if deregulated GE crops are grown here now so we are unable to assess possible local effects.

However, GE research is currently being performed on a number of crops characteristic of and routinely grown in Santa Cruz, including our high value crops of strawberries, raspberries, broccoli, lettuce, apples, and various ornamental flowers. GE research is being done on other local crops of cucumbers, onions, peas, peppers, pumpkins, grapes, squash, sweet corn, tomatoes, avocados, persimmons, plums, and walnuts.

There is no publicly funded GE research being performed in 2004-2005 according to a FOIA request to APHIS. Any knowledge of past public research would require a specific FOIA request for each year. We have no clear way to determine if there is any privately funded research either now or planned in the future.

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[1] USDA 2005. Global Traceability and Labeling Requirements for Agricultural Biotechnology-Derived Products: Impacts and Implications for the United States. www.ucbiotech.org

[2] http://www.tradeknowledgenetwork.net/pdf/tkn_domestic_regs_sum.pdf. Additional trade information may be available via the following link to USDA Foreign Agricultural Service information about other countries and biotechnology. http://www.fas.usda.gov/itp/biotech/index.html

[3] Ibid

GE or GMO crops that may be deregulated and ultimately planted and grown in this county for commercial purposes may carry possible negative impacts (i.e. gene flow, contamination) for both non-GM and organic growers. Spatial (buffers) and temporal (time of planting and maturity) separation strategies could be used to alleviate or minimize some of the potential negative impacts but the actual effects of such strategies remain undetermined.

Crop recall and destruction costs may be incurred if a crop delivered to market is found unsuitable for the intended market. Commercial, conventional, and organic growers are all held to the same U.S. agricultural grades and standards. Organic growers must adhere to additional regulations to meet that market's requirements. If, for example, an organic crop was found to contain GM material or a country, with GE prohibitions, detected a crop with GM material, that crop may be rejected. Generally, costs for recalling commercial agricultural products have traditionally been borne by the grower. Additional cost would include transportation and destruction of the rejected crop. In some instances, the cost of destroying a GE contaminated food product has been borne by the taxpayers.[1]

Impacts Specific to Organic Production

Organic production is governed by federal and state regulations, and, in the case of exported products, international regulations. GE is prohibited in all cases. Two potential economic or market impacts are noted here:

If shown to be contaminated by GE crops, there is a loss of market or price premium (difference between organic and conventional price) or organically produced crops. There is also the potential for loss of confidence in the marketplace for organic products if GE contamination of organic crops occurs.

Specific dollar amounts are difficult to assess or measure because organic premiums vary by crop and varying market conditions. A USDA Economic Research Service report indicates that wholesale organic price premiums are narrowing for some products, and remain strong for others [2]

Another serious concern for organic growers would be the loss of organic certification and registration. Certification and registration of organic operations in California are comprehensive processes that generally require a three-year conventional-to-organic transition period. During this time agricultural products may not be labeled or sold as organic. Certification/registration costs differ depending on the process and the fee structure associated with the certifying agent and the characteristics of the operation itself. Because of 'agent and site specificity', it is difficult to assess or measure the potential economic costs associated with the loss of organic certification.

Many growers, both conventional and organic, lease their land. Certified organic growing areas generally are rented at a higher rate. There would be possible additional costs for organic growers who lose certification due to GE contamination.

Effects on Market Reputation

Should food and horticultural crops using GE technology become commercially available and planted in Santa Cruz County, some negative effects to market reputation for local organic and conventional farmers who wish to remain 'GE free' would occur. Buyers and consumers could be reluctant to purchase commodities if gene flow or contamination is perceived (or confirmed).

[1] U.S. Department of Agriculture. 2001 "USDA Purchases Cry9C Affected Corn Seed from Seed Companies" Press Release, Washington, DC (June 15).
[2] http://www.ers.usda.gov/publications/vgs/may05/VGS30801/VGS30801.pdf

Loss of Market Due to Consumer Rejection

Consumers' unwillingness to purchase genetically engineered food has been particularly strong in Western Europe and Japan, both of which are major export markets for US farmers. This can lead to loss of markets due to consumer rejection.

These regions and a number of other governments around the world have enacted labeling regulations, or even bans/moratoriums on GE crops. (See **Appendix 5** --Other Countries' Requirements for GE Crops)

Large food processors in the United States have announced that they would use non-GE ingredients in their products, including Frito-Lay, McDonald's, Heinz and Gerber (the latter two for baby food only). This has led to the development of separate production and processing systems for genetically engineered crops and their conventional counterparts, such as corn and soybeans, with price premiums being paid for non-GE varieties.

Contamination of these crops with GE varieties could result in the loss of this price premium, or the loss of markets to sell the product altogether. Such impacts have already occurred for some organic farmers. Certified organic is one of the fastest growing segments of the food industry, with sales growth rates of twenty percent a year since 1990 and these products are typically sold for higher prices than their conventional counterparts.

For example, Terra Prima, an organic food processor, recalled 87,000 bags of organic corn chips that were contaminated with a GE variety (*Bt*) in 1998, at a loss of $200,000. In addition, nearly all organic farmers in Saskatchewan, Canada have stopped growing canola (a major commercial crop in this province) since GE varieties were introduced, prompting the Saskatchewan Organic Directorate to file a class action lawsuit against Monsanto and Bayer Crop Science in 2002 for their economic losses.

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Enforcement Costs

It is difficult to predict the size of the workload for enforcement of either labeling of GE products or a moratorium or ban of GE crops.

Whether under the supervision of the County's Agricultural Commissioner, the Health Department, or some other agency, someone will be needed to investigate complaints, take samples, issue citations or notices, participate in or hold hearings and supervise any necessary abatement. A senior inspector's annual salary would be approximately $84,000.

It is difficult, at this time, to predict the actual cost of testing crop or seed samples, additional monitoring, legal, and administrative cost. Anticipating an annual budget of up to $150,000 would be prudent.

The various GMO ordinances adopted in Marin and Trinity Counties and defeated in other counties included provisions that require violators to pay for the costs and expenses related to enforcement, abatement and monitoring costs. They also assessed varying civil penalties. While Santa Cruz County would have to budget for enforcement of a moratorium, a portion of this expense could be recoverable from any party who willfully disobeys such an ordinance.

Higher Productivity

Several research studies contend that higher yields, decreased pesticide use (or both) translate into higher profitability for farmers using GE crops. It is important to note that these studies pertain to the major field crops already deregulated (cotton, corn, soybeans, canola) for use in commercial plantings. Because horticultural crops have not been planted or studied on the scale of their deregulated field crop counterparts, we cannot assess GE horticultural crop productivity at this time.[1]

[1] NCFAP Plant Biotechnology: Current and Potential Impact for Improving Pest Management in U.S. Agriculture:

Yields for Roundup Ready soybeans are consistently lower than conventional varieties. This is not surprising since they were developed for an unrelated trait, herbicide resistance.[1] Several GE crop varieties including *Bt* cotton have also experienced dramatic, unexplained crop failures.[2]

There is disagreement about GE and pesticide reduction. Using USDA data, Charles Benbrook, (former Chairman of the Board on Agriculture of the U.S. National Academy of Science and agricultural staff expert on the Council for Environmental Quality, Carter Administration) found that American soybean farmers using Monsanto's Roundup Ready Soy are applying more herbicide than non-GE farmers.[3]

Rapid Technological Change and Flexibility to Respond to Changes

There is no question that agricultural biotechnology is rapidly evolving in both the science associated with the technology and the general public's knowledge and understanding of it.[4] GE for agricultural crops is considered a relatively new 'tool' that might help farmers solve current or emerging problems such as pest management (i.e. virus resistance, insect and weed management).

To the best of our knowledge, no economic studies have been performed to assess potential costs or benefits specifically related to environmental risks and GE crops.

Constraints to research, development or the commercial use of GE may have the effect of stifling innovation and ultimately have implications for U.S., California, and local economic competitiveness in agriculture. However, environmental risks, and other potentially unknown risks, may also be associated with GE crops and could potentially have a negative impact on for U.S., California, and local economic competitiveness in agriculture.

Potential Sources of New Products

Several research articles point to the challenges or barriers associated with developing 'second generation' GE horticultural crops. These include increased costs for research and development, trade barriers, and market acceptance (by consumers, producers, and processors.)

Trade restrictions and market acceptance can take on many forms including food safety (allergens), the ethics associated with GE, and product integrity (knowing where and how a product is grown).[5] For 'first generation' GE deregulated field crops (soybeans, corn, canola and cotton) large acreages and market size may have justified such expenditures in the past. It is not clear if these barriers will be overcome or justify the investment funds necessary to research and develop 'second generation' horticultural GE crops.[6]

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[1] Benbrook 1999, 2001a

[2] Klinkenborg 1997, Coghlan 1999

[3] Charles Benbrook, "Troubled times amid commercial success for Roundup Ready soybeans," May 2001. www.biotech-info.net/troJ.J.troubledtimes.html

[4] For more information on consumer knowledge of GM (GE) crops, see James. 2004. Consumer Knowledge and Acceptance of Agricultural Biotechnology Vary; California Agriculture Vol. 58. No.2. http://californiaagriculture.ucop.edu/0402AMJ/toc.html).

[5] Sumner. 2004. World trade rules affect horticultural biotechnology. Alston. 2004. Horticultural biotechnology faces significant economic and market barriers: California Agriculture, Vol. 58. No. 2

[6] Redenbaugh and McHughen. 2004. Regulatory challenges reduce opportunities for horticultural biotechnology. California Agriculture, Vol. 58. No. 2.

5. Ecological and Environmental Considerations
(see **Appendix 7** for complete references)

While there are countless studies that weigh the risks and benefits of genetically engineered crops, the full impacts of GE organisms on the natural environment are difficult to assess because they require an extended amount of time and meticulous monitoring. Environmental risk assessment studies were not required to be conducted by law before the first GE crops were commercialized in the US.

When reviewing the literature, there is a broad range of interpretation and opinion of the carefully conducted studies. Below is a brief review of risks gleaned from a range of environmental and ecological considerations in laboratory and field studies that have been conducted on the environmental effects of genetically engineered crops. Several references were very valuable in assessing the environmental considerations.[1]

The technology, as a tool, has potential benefits. However, for the purpose of this report, the risks must be assessed to ensure the diverse environment of Santa Cruz County will be protected from any unnecessary ecological damage due to any use of genetically engineered organisms.

Genetic Pollution

Gene flow and the risk of creating plant species with genetically engineered traits is of great concern in any ecosystem. The movement of pollen and seed by pollinators and wind can spread a trait within the same species and to near relatives, weeds and feral plants. This can also be facilitated by human error due to transportation spillage, weakness in processing machinery or in the manual segregation of seeds.

In the process of genetic engineering and in the unintentional transfer of herbicide, biotic- and abiotic-stress tolerance genes to weeds and local flora, the factors of the distance of pollen movement, synchrony of flowering, sexual compatibility, reproductive biology and the ecology of the recipient plant needs to be considered.

The risk of pollen movement by pollinators is a considerable risk. Studies of pollinators, especially bumblebees and their foraging practices, find the bees traveling up to a third of a mile and not being inhibited by natural landscape barriers.[2] This poses a risk to transgenic crops grown in high densities in large areas. Because agriculture lands are attractive forage grounds, the buffering by forests or other landscape obstacles are not a deterrent to pollinator activities.

Second, various cultivated crops, i.e. oilseed rape, barley, wheat and beans, can hybridize with weedy relatives.[3] The consequence of the transfer of novel genes from GE crops to weeds depends on the nature of the novel gene and the biology of the recipient weed. It is very difficult to inhibit this gene flow and will require a firm knowledge of surrounding flora, careful monitoring and physical removal of these novel plants before maturity to prevent possible contamination.

Third, problems of gene flow arise when crops containing different herbicide-tolerance genes become multiply tolerant to several herbicides by pollination between adjacent crops. In Canada, farmers have detected oilseed rape plants tolerant to three different herbicides. Two of the novel genes were from GM crops and one from conventional breeding.[4] Volunteer canola plants have been found to be resistant to multiple herbicides (commercial seeds are only resistant to one herbicide) through pollen flow resulting

[1] Dale, Clarke, Fontes, 2002; Barton and Dracup, 2000; Wolfenbarger and Phifer, 2000; Fruits of Biotechnology 2004; Arntzen, 2003
[2] Kreyer, *et al*, 2004
[3] Rieger, *et al*, 2002; Watrud, *et al*, 2005; Friesen, Nelson, Van Acker, 2003
[4] Orson, 2002

in 'gene stacking'.[1] Therefore, when growing GE crops, agriculture practices and weed control needs to be rigorously managed.

In 2004, genes from genetically modified corn were discovered in Mexico's native maize, the source of tremendous natural genetic diversity. Maize originated in Mexico and is comprised of 59 races, each with a large number of sub-varieties. Over the centuries, maize has been bred to grow in hot, drought-prone valleys to cool and wet mountain areas (and everywhere else in between) with a remarkable number of colors, sizes, textures, uses and flavors. From this array, plant breeders have developed new maize varieties with wide ranging traits that are easy for farmers to grow.

Introducing GE corn varieties into the world's center of biological diversity could substantially reduce the genetic diversity that exists there. Cross breeding, or 'gene flow' of GM corn with native maize could create hybrids that may be highly competitive and displace native varieties.[2]

Escape Organisms (Contamination of Other Plants)

It is important to determine if each GE trait makes a crop more likely to be "weedy" in agriculture habitats or more invasive in natural habitats. Careful attention needs to be paid to crops that already have "weedy" characteristics or when added genes are expected to improve crop competitiveness. With these situations, the chances increase for escaped organisms which would result in contamination of other plants and fields (organic, conventional or native).

The transfer of herbicide-tolerance genes to weed species has been well documented.[3] The use of glyphosate herbicides has increased with the introduction of glyphosate-tolerant GE crops. This is shifting weed populations to become tolerant to this herbicide. Rigorous case by case studies are needed to monitor escape organisms and prevent the risk of creating "superweeds".

These "superweeds" can develop resistance to herbicides by constantly being sprayed with the same herbicide as the cultivated crop and this developed resistance is more of an evolution rather than by gene flow (pollination) from herbicide-tolerance crops. Glyphosate-tolerance was considered to be highly unlikely to evolve in weed species in this way. However, there are examples of annual ryegrass in Australia[4] and horseweed in the US[5] that are now glyphosate-tolerant after increased use of herbicides. Other researchers have confirmed fifteen weed populations resistant to this herbicide.[6] Farmers report resorting to the use of a more persistent and toxic herbicide, 2,4-D, to control these 'superweeds'.[7]

The question of the development time to create resistant *Bt* crops has been addressed and the research suggests there must be much effort to sustain the genetically engineered crop to reduce contamination of other insects and plants.[8] With the commercialization of insect resistance genes, the EPA created a list of recommended agriculture practices to prevent the creation of *Bt*-resistant insects.

The favored resistance management strategy in *Bt* maize is the 'high-dose/refuge strategy'. This is a recommendation to provide refuges of host plants that do not produce *Bt* toxins in the field. One laboratory study of the EPA's recommended agriculture practice of 'high-dose/refuge strategy' suggests the practice might not be effective with some insects or variations of the *Bt* toxin and allow for the eventual evolution of *Bt*-resistance.[9]

This potential problem is based on genetics and incomplete dominance of some resistance genes as apposed to being completely recessive as assumed. In addition, it is important to note that a survey of

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1 Beckie et al 2003
2 http://pewagbiotech.org
3 Willenborg and Van Acker 2006; Gustafson, *et al* 2005; Matus-Cadiz, *et al*, 2004
4 Pratley, et al, Glyphosate Resistance in Annual Ryegrass. 1996
5 VanGessel, 2001
6 Nandula, *et al,* 2005
7 Steward 2000
8 Huang, *et al*, 1999
9 Liu, *et al*, 1999

US maize growers in the US found almost thirty percent of the farmers failed to comply with the refuge protocols designed to prevent or delay the onset of resistance.[1] With almost a third of corn farmers not taking precautions, the risk of resistance increases.

A lawsuit has been filed seeking to force the Agricultural Department to do an environmental impact study of alfalfa seeds which have been genetically modified to be resistant to glyphosate (e.g. Round-Up). The alfalfa seed in question, developed by Monsanto, is the second GE perennial crop approved by the government for wide scale commercial production. This Monsanto seed was planted on 50,000 acres last year and seed for an additional 90,000 acres will be available this spring.

Alfalfa is easily cross-pollinated by bees or the wind and pollen can travel up to two miles from its source. Plaintiffs who are suing to prevent GE contamination contend that this seed threatens to eliminate the conventional alfalfa industry. Deregulated GE alfalfa is not required by law to be isolated to prevent cross-pollinated other alfalfa fields.

USDA officials argue that they considered the issues contained in the lawsuit before they approved the crop and believe that it is unlikely that there will be any problems because alfalfa is harvested before it goes to flower. The USDA also contends that it is up to the potentially contaminated growers to avoid cross-pollination and not the other way around. Plaintiffs contend that farmers who are growing seed for either the conventional or organic markets will have major problems.

Non-Target Kills

Chemical toxicity to living organisms is a direct impact of novel GE traits. The non-target effects of insect resistance genes are possible especially when the beneficial insect is closely related to the target pest or when a predator ingests prey feeding on plants expressing GE traits. In addition, those organisms found in the soil are also at risk to long term exposure.

The *Bt* genes and their toxic properties have been greatly studied in the laboratory. Some studies have focused on the effect of constitutive expressed insecticides in crop plants encompassing large areas of land. The non-target organisms that are of similar families inhabit agriculture ecosystems and are at risk.

The classic, controversial case study has been on monarch butterfly larvae.[2] The larvae of the butterfly were fed doses of *Bt* expressing corn pollen dusted over milkweed. After four days, 44% of the larva died. While this highly profiled study did not assess ecological consequences, it raised many questions and resulted in a flurry of studies.[3] These studies were comprised of laboratory and field analysis of the impact of *Bt* containing corn pollen and butterfly populations.

Other studies have looked at the effects of GE *Bt* crops on pest predators.[4] Lacewings, which are natural predators of corn borers, that were reared on corn borers that had ingested corn leaves expressing *Bt* toxin showed increased mortality and delayed development. These types of studies confirm beneficial insects are harmed when feeding on pollen from crops engineered with the *Bt* toxin genes. What are more difficult to discern is the non-target effects of insect resistance genes in the field due to dynamic ecosystems. One must also take into consideration the effect and direct harm that comes to the non-target and beneficial organisms with the direct use of pesticides.

Another consideration is to the fate and consequence of insecticidal toxins which persist in the soil and ground water. It has been shown that *Bt* plants exude *Bt* toxins from their roots during their entire lifecycle and from residual material after harvest.[5]

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[1] Dove, 2001
[2] Losey, Rayor, Carter, 1999
[3] Zangerl, *et al.* (2001); Oberhauser, *et al*, 2001; Pleasants, *et al*, 2001; Hellmich, *et al*, 2001; Stanley-Horn, *et al*, 2001; Sears, et al. 2001; Ag Biotechnology Stewardship Technical Committee, 2001
[4] Hilbeck, *et al.* 1998
[5] Carrierre, *et al.* 2001

The bioaccumulation of the GE plant material that persists after harvest, year after year and the effect it has on soil species and microorganisms has the potential to be ecologically damaging.[1] The toxins can bind to elements in the soil, stabilize and remain active for hundreds of days.[2] Since most of the studies focus on four major commodity crops with herbicide and insect resistance genes, it is a good chance to measure soil ecosystems for risks over time. Research is underway that will give more evidence as to the outcome of time versus exposure to these novel traits in the soil and groundwater.[3] This should give insight as to potential risk on the non-target ecosystems in contact with the GE crops.

Loss of Biodiversity

Some effects of GE organisms could cascade through the food web of an ecosystem thus reducing biodiversity and disrupting ecosystems. The indirect impact of GE crops and the changing agriculture practices on the environment results in the reduced efficiency of conventional pest, disease and weed control. This can be facilitated by increased herbicide use, more frequent sowing of GE crops and an increased use of minimal cultivation.

Effects on wildlife can be attributed to loss of diverse food sources and greater use of broad-spectrum herbicides. Different herbicide use programs will have different effects on plant and animal biodiversity in fields and field margins. Soil and water biodiversity are mostly effected by herbicide and pesticide use. Some studies suggest this is not the case because GE crops reduce the use of herbicides and pesticides, whereas some studies suggest the opposite, in that increasing the use of GE crops increases the use of the herbicides and pesticides, especially when the seed and herbicide are sold as a package.[4]

Purity of Local Production

It seems next to impossible to make a GE-free claim in regards to a harvested crop or seeds until the testing methods become more precise.[5] The spread of genetic pollution is growing and farmers have to go to great lengths to preserve the purity of their crops. The solution is not clear and to date relies solely on each farmer (GE, conventional or organic) to be vigilant over their crops while working with neighbors to protect the organic and conventional (non-GE) crops from the GE crops.[6]

The area of testing for the presence of GE traits in agriculture crops and products is going to have to grow and be relied on heavily to provide assurance to growers and consumers that the purity of local production be maintained and guaranteed. Currently, it is the responsibility of the farmer to maintain the purity of their crops. It is a daunting task to fight against natural processes to ensure genetic uniformity. (This topic is also addressed in the **Liability** section of this report.)

Unintended Consequences

The variable and unexpected results with potential ecological damage have to be identified on a case by case basis and tailored risk assessments are imperative. Ecosystems are complex and dynamic. One concern is the recent advancement of GE perennial crops. To date papaya and alfalfa are the two commercially grown perennial GE crops. The problem with alfalfa is that it is easily cross-pollinated by bees and wind and pollen can travel two miles from the source. Strict isolation farming practices are needed.

Another concern is that of the threat of new bacterial and viral diseases evolving. Evidence from laboratory tests suggests that the evolution is possible and to date no data supports the occurrence in

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1 Dunfield and Germida, 2004
2 www.epa.gov/scipoly/sap/2000/october/octoberfinal.pdf
3 Dale, Clarke, Fontes, 2002; Barton and Dracup, (2000); Wolfenbarger and Phifer, 2000 ; California Agriculture (April-June 2004)
4 Crawley, *et al*, 2001;
5 Michael, 1999
6 Miller and Kilman, 2005

natural conditions.[1] However, with the use of engineered antibiotic resistance genes and viral coat proteins, there is the opportunity for recombination of the transgene with other bacteria and viruses present on the host plant. And as stated before, the indirect effect of GE bioaccumulation after generations and years needs to be carefully reviewed in hopes to direct the development of the next wave of GE crops, especially more specialized horticulture crops.[2]

[1] Syvanen, 1999; Dale, Clarke, Fontes, 2002
[2] Kaufman, 2001

6. Health

Introduction

Genetically engineered foods and food products are the result of a relatively new and evolving biotechnology affecting American agriculture. Many that have advanced GE technologies argue that it has the potential to improve resistance to disease, pests, and adverse growing conditions; introduce new products with increased yields and nutritional qualities; and increase food security.

However, the impact of agricultural biotechnology on human health is largely unknown. Many questions are being raised about the safety of GE foods in terms of the potential for unintended compositional changes that may result in allergen production, nutritional or toxicological ill effects, or the promotion or unmasking of genetic vulnerabilities to certain compounds in food resulting in diet related diseases such as celiac disease (gluten sensitivity) or hemosiderosis (iron overload).

Although “genetic modification” and “genetic engineering” are sometimes used interchangeably, this subcommittee strictly defined its concerns as limited to genetically engineered (GE) food crops. Genetic modification can occur in a number of processes both natural and manipulated that alter the genetic composition of plants, animals, and microorganisms.

Genetic engineering, on the other hand, refers only to recombinant deoxyribonucleaic acid (rDNA) methods that allow a gene from any species to be inserted and subsequently expressed in a crop of a related or unrelated species. The transfer of genes between unrelated species can only happen using GE technology and not through the use of traditional plant breeding techniques. Recombinant DNA technology combines genes from different organisms into novel genetic material.

This distinction between genetic modification and genetic engineering is important as there are relative likelihoods of unintended genetic effects associated with various methods of plant genetic modification.

The least likelihood of unintended adverse effects involves conventional breeding methods from homogenous populations. As genetic engineering allows for the forced transfer of rDNA from any species, the induced mutagenesis is most genetically disruptive and consequently, more likely to display unintended effects. This report focuses on the potential unintended consequences of human consumption of genetically engineered food crops.

Food Safety Analysis

The analysis of the food crop or product itself is done in two ways: First, targeted quantitative analysis that quantifies a pre-determined compound or class of compounds, e.g. assessment of nutritional components such as saturated fat; and second, profiling methods that use advanced chemical and genetic profiling techniques to identify and quantify all compounds present in a biological sample.

Both of these methods are done in the pre-market period prior to commercialization and usually seek to compare the GE food with its conventional counterpart. This food safety evaluation relies on the concept of Substantial Equivalence which states that if a GE food can be shown to be essentially equivalent in composition to an existing food then it can be considered as safe as its conventional equivalent.

The FDA's "substantial equivalence" standard advises that GE foods are analyzed for the presence of a few nutritional components, such as essential vitamins and minerals, fatty acids, carbohydrates, proteins, and a handful of known allergens. The standard does not require testing for presence of potential toxins, mutagens, carcinogens or new allergens created during the production of GE foods. Only a GE food that is determined not to be “substantially equivalent” to its conventional counterpart is subjected to a highly detailed safety assessment.

However the criteria and objective standards for this safety assessment have not been universally established such that the very concept of Substantial Equivalence has been criticized as subjective and inconsistent.[1]

Health outcomes could be associated with the presence or absence of specific substances resulting in unintended compositional changes affecting nutritional components, toxins, toxicants, allergens, or anti-nutrients.

At present, the state of the science is not advanced to reliably detect changes that may result from the introduction of a gene or multiple genes in terms of previously unknown toxins, anti-nutrients or allergens.[2] An example is the Showa Denko case, in which 37 people died, 1535 were left permanently and severely disabled, and another 5000 were temporarily disabled due to ingestion of l-tryptophan, a staple supplement in health food stores thought to be a safe, nonaddictive treatment for insomnia.

Showa Denko changed their traditional method of production to a GE approach which was tested to be 99.6% pure and substantially equivalent to the conventional l-tryptophan. However, pre-market undetected specific trace contaminants in the GE process were thought to be the cause of the death and disability that resulted from ingestion of the GE product.[3]

Another important example of unintended side effects are the demonstrated changes caused by transgenic alfalfa to soil bioforms, crucial to the nitrogen fixing process for many crops.[4]

While nutritional assessments have been made as part of the safety assessment of a GE food, full nutritional assessment in human subjects has not been done with particular attention to vulnerable groups such as infants, children, pregnant and lactating women, the elderly, and those with chronic disease. Studies have also not been done in populations that have particularly high intakes of specific GE foods which mostly likely comprise lower income populations who tend to eat more processed and less organic foods.

The relationship between adverse health effects related to food intake and genetic variability is well documented. An example is celiac disease caused by gluten sensitivity. Gluten is found in wheat, barley, and rye. The extent of genetic susceptibility to various foods is really unknown as illustrated by celiac disease surfacing in populations being initially exposed to gluten in food products in significant amounts as has happened with the introduction of northern European foodstuffs in Asia.

The unmasking of these genetic predispositions accompanies marked changes in the food supply. The contribution that GE foods may make to this area of potential adverse health effects is unclear and point to the need for more extensive, post-market, technically advanced studies.[5]

Food allergies occur in 1-2% of adults and 6-8% of children.[6] Introduction of a new gene in to a plant may cause that plant to become allergenic. Therefore known allergens should not be introduced into food crops. Many common foods in the American diet cause allergy: corn, eggs, soy, rice, wheat, brazil nuts, peanuts, seafood, and milk.

Principal GE crops are soybeans, corn, cotton, and canola. Two of these crops are major allergens and their relationship to either the decrease or enhancement of allergenic potential has not been thoroughly

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[1] Millstone E P, Brunner E J & Mayers S (1999). *Beyond "Substantial Equivalence".* Nature 401, 525-26

[2] The Royal Society February 2002. *Genetically Modified Plants for Food Use and Human Health—An Update*

[3] Boyens I (1999) *Unnatural Harvest. How Corporate Science Is Secretly Altering Our Food.* Doubleday, Toronto, Canada.278pp

[4] Di Giovanni G D, Watrud L S, Sidler R J, Widmer F (1999). Comparison of Parental and Transgenic Alfalfa Rhizosphere Bacterial Communities Using Biological GN Metabolic Fingerprinting and Enterobacterial Repetitive Intergenic Consensus Sequence-PRC (EPIC-PCR). Microb. Ecol. 37:129-139

[5] National Academy of Sciences. Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects. (2004)

[6] Metcalf D D, Astwood J D, Townsend R, Sampson H A, Taylor S L & Fuchs R L (1996). *Assessment of the Allergenic Potential of Foods From Genetically Engineered Crop Plants.* Critical Reviews in Food Science and Nutrition 36(s), S165-186

studied. The GE soy strain that eliminates the P34 gene in soy has been shown to not evoke an antibody response in persons allergic to that particular protein in soy.

Potential Health Impacts

As stated, the science of analyzing the effects of GE is relatively young. However, there are published reports of multiple deleterious effects of GE food on the immune systems and fertility of laboratory animals. In addition, scientists have expressed concern about the creation of new allergens, toxins, carcinogens and potentially novel infectious diseases during the synthesis of GE organisms. Below is a list of some key studies that have been conducted to date:

- Lower/altered nutritional profile (Lappe et al. 1999)
- Allergens (Nordlee et al. 1996; Hogan & Foster, 2005)
- Toxins (Pryme & Lembcke 2003)
- Immune effects (Prescott et al. 2005; Bernstein et al., 1999)
- Carcinogenic effects (Epstein 1996; Ander et al. 2002; Holmes et al. 2002))
- Altered fertility (Stoger et al. 2002)
- Increased antibiotic resistant bacteria (Netherwood et al. 2004)
- Potential novel infectious diseases (Ho et al. 1998)

Conclusion

Until there is a body of sound science upon which to form a rigorous basis for hazard identification that defines and standardizes the phenotypic characteristics, including, but not limited to, composition, nutritional value, allergenicity, and toxicity; and until there are more sensitive profiling techniques that could appropriately characterize the differences between a GE food and its conventional counterpart, it would seem justified to proceed with caution in regard to the introduction of genetically engineered food crops in Santa Cruz County as the unintended health effects of such food is substantially unknown at the present time.

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7. Liability

There are many potential sources of genetic contamination of conventional and organic crops by GE organisms: genetic drift caused by wind, insects, mammals, humans; commingling arising from shared equipment; commingling during the handling, milling, and processing stages; and, volunteer crops coming up in subsequent years (which can also lead to inter-crop contamination when fields are rotated).

This makes it essential to consider the question of liability for resulting market losses that can arise from contamination. When looking at liability issues surrounding GE materials it may be helpful to go over some basics of the establishment of liability.

Liability may be established by statutory or by common law. A party may seek to establish liability when that party has been harmed in some manner. Statutory liability may be a case for an enforcing authority, such as an Attorney General, District Attorney, or other law enforcement personnel.

To our knowledge there are no statutes containing liability provisions to protect farmers if their crops become contaminated with GM organisms. A plaintiff may be able to seek damages from a defendant in a civil lawsuit with private attorneys based on tort law. In the case of GE contamination the following tort claims might be made:

Trespass to land: Arises when someone intentionally enters another person's land and causes damage. This claim could be made if a farmer or seed company knew that genetic traits from a GE crop would enter a neighbor's property, and genetic drift in fact occurs, causing harm to the neighbor's crop. This claim has been made in numerous cases with pesticide drift from aerial spraying.

Nuisance: Occurs when someone interferes with another person's use and enjoyment of his or her property. The interfering act does not need to cause property damage. GE contamination could affect what crops a neighboring farmer can grow, thereby interfering with the farmer's ability to use his or her property. This could also include an actual loss of value in farmland.

Negligence: When a person fails to act reasonably under the circumstances and this failure causes harm to another. To prove that GE contamination was the result of negligence, a person would have to prove that a neighboring landowner had a duty to prevent GE contamination and that there was a reasonably foreseeable likelihood of injury. Failure to select seed properly, adhere to specified buffer zones, or follow growing and harvesting procedures could mean a breach of duty. If one of these failures is linked to another person's injuries, the farmer or seed company that caused the GE contamination could be liable for negligence.

Strict liability: Arises when someone engages in abnormally dangerous activity. Some legal scholars argue that if a farmer and/or seed company knows that a GE crops is difficult to control and that it will likely cross-pollinate with crops in adjacent fields, the farmer and/or seed company should be held strictly liable for any resulting damages.

Establishment of liability may lead to compensation to the harmed party and may also establish legal precedence. Harm may be economic, to people, or to property. We can assume that most harm to farmers will be in the area of economic loss, some to property, and little to personal.

As a means to understand these legal principles as they relate to GE materials we would like to look at a couple of situations that focus on the issue of liability as it relates to the practice of agriculture.

What Happens When a GE Material Contaminates a Non-GE Crop or Food?

A buyer (country, processor, broker, etc) can reject a crop because the crop is found to contain GE plant materials in an amount high enough to exceed the buyer's specifications.

***Discussion*:** A number of countries test for the presence of GE materials in all commodities arriving for import and reject commodities that contain any unapproved GE materials.[1] The reasons vary but include a desire not to consume unapproved GE materials, a concern that their own GE research and programs may be compromised by "foreign" materials, or that their farmers may plant the commodities and introduce GE material into the indigenous crops of that country. Processors, organic and conventional, may test and reject crops based on the presence of GE materials. Finished products have been tested and recalled due to the presence of GE materials.

Economic harm is obvious in the cases above and may be visited upon all parties to the transactions. Buyers may suffer economically and wish to collect from the farmer for the costs associated with purchase and shipping among others. Processors would have similar claims and also may include recall costs and lost production. The farmer has lost a sale and maybe the ability to do business in the future. Even if the farmer did not intend to defraud the buyer and was not negligent she/he may still be found to be in violation of a contract or foreign statute and forced to pay. In such a case as above the farmer may not have knowingly planted a GE crop or the crop may have been contaminated by drifting pollen. In these cases the farmer may wish to pursue the producer of the GE seed or the neighboring farmer growing the crop that caused the contamination.

As detailed above, to receive compensation for loss the farmer or buyer has two avenues.

- Ask an enforcing authority to bring charges either against the holder of the original GE patent and/or a neighboring farmer growing the GE crop that was responsible for the contamination for violation of existing law. Once again, to our knowledge there are no laws in the US that directly addresses the cross contamination by GE materials of other or non-GE crops.

- The farmer or buyer might pursue a civil action against these two or more parties seeking to establish liability for loss. As mentioned above case might be made on the basis of trespass, nuisance, or other defined acts. If harmed, a farmer must develop his own case, using one of the legal claims described above, and test it in court.

To date, no legal precedents exist that would be helpful in assessing the likely outcome, and it is likely that the farmer would have to bear the financial, practical and psychological burden of attempting it. Even if a farmer were to file a complaint under one of these categories, it would be years before the courts even established that such a legal theory is valid. This would be an unlikely scenario considering the uneven resources available to the various parties. In any case the original GE seed seller most likely has secured from the GE farmer a contract limiting the seller's liability through indemnification

It is unlikely, but there may be insurance coverage held by one or more parties for the above loss. Insurance companies generally seek to settle and avoid going to court. While the parties in such a settlement may agree certain facts, liability, in fact, is seldom established.

Can a Farmer Lose Organic Certification Due to the Presence of GE Materials in or on the Land or Crop?

***Discussion**:* The National Organic Program enabling legislation is mute on this issue except to say that a certified organic farmer may not knowingly use GE materials in production of an organic crop. Because of the lack of clarity it has been assumed by some that if the farmer has not knowingly used the GE materials that the crop may still be legally considered as organically grown.

However, if detected, the presence of GE materials would most likely lead to the rejection of the crop by a buyer. Subsequent to GE contamination of a crop, certifiers have begun to decertify the farm involved. In terms of the integrity of the organic product, as stated by the USDA, the status of organic products "is left to the buyer and seller to resolve in the marketplace through their contractual agreement."[2] Once

[1] See **Appendix 5,** Other Countries' Regulations for GE Crops

[2] National Organic Program http//www.ams.usda.gov/nop/q&a.html

again economic harm is obvious in this situation, along with the potential loss of property values due to contamination and decertification. As far as remedies go, see the discussion above.

Farmer's Unauthorized Use of Patented Material

A farmer, knowingly or not, takes advantage of the benefits of a GE patent. If, for example, a GE crop is resistant to a certain fungus and those GE traits have migrated to a neighboring crop and that farmer is able spray less.

Discussion: The neighboring farmer could be held to have benefited from the traits of resistance breed into the patented material without paying for the use of that patent. Essentially this would be unauthorized use of the patented material. As a result, there could be a civil case brought by the patent holder against the farmer. If the patent holder prevailed case law precedent may be established. Uneven resources should work in the plaintiff's favor.

The situations described above are the most obvious and simple examples. It doesn't take too much imagination to see how things could get very complex from here. For example, a class action suit is filed against a processor and grower for undisclosed GE material in baby food. The plaintiff could allege negligence and lack of care for not detecting the GE material.

The law as it relates to liability is very complex. Without a clear a cross the board acceptance of the presence of GE material in foodstuffs, combined with the varying regulations on import trade by countries around the world legal action is inevitable. How the farmer fairs in the legal melee will depend on the enacted statutes or lack there of, and the establishment of case law. Individual growers may be hampered in their ability to go to court due to the financial resources needed.

We believe the following information to be also germane to the subject:

No specific information on legal remedies protecting farmers from lawsuits and patent infringement claims could be found. Legal precedents to date have placed the burden on the farmer to prove that they have not knowingly or unknowingly violated the terms of GE seed technology use agreements. The Farmers Legal Action Group's *Farmers Guide to GOMs*[1] describes actions that farmers should take if a GE seed company investigates them for possible patent infringement, but other than to advise that farmers take their own independent samples and hire a lawyer to represent them, there is no mention of legal remedies.

There are, however, many cases of farmers sued by Monsanto for patent infringement. These are described in a report entitled *Monsanto vs. U.S. Farmers.*[2] Monsanto is by far the largest player in seed biotechnology, controlling 90% of the world's GE seed patents on the market. They have also been aggressive prosecutors of farmers for patent violations, with a department of 75 employees and a $10 million annual budget devoted to investigating and prosecuting farmers, at an estimated rate of 500 or more cases every year[0]. To give an indication of the scale of these suits:

- The largest recorded judgment made in favor of Monsanto is $3,052,800
- Total recorded judgments granted to Monsanto amount to $15,253,602
- For cases with recorded judgments (note that many are settled out of court, or under gag order), farmers have paid a mean of $412,259

Farmers have been sued by Monsanto under many different circumstances. As described in *Monsanto vs. U.S. Farmers*, they have included:

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[1] *Farmers Guide to GMOs*. 2004. Farmers Legal Action Group (FLAG). www.flaginc.org.
[2] *Monsanto vs. U.S. Farmers*. 2005. Center for Food Safety. www.centerforfoodsafety.org.

- Farmers who unknowingly planted and/or sold Monsanto seed
- Farmers who never signed the technology agreement but saved seed (at least 6 of 90 recorded lawsuits brought by Monsanto involved the forged signature of the farmer)
- Farmers who signed the technology agreement and saved seed

One important legal/liability question is the following:

What obligations and legal limitations do farmers assume when they sign GE contracts? In partial answer to this question, the following information is obtained from the Farmers Legal Action Group's *Farmers Guide to GMOs.*

Biotechnology companies and seed companies require farmers to sign technology use agreements that generally give the farmer rights to use, or "license," the GE seed in exchange for complying with the company's production methods and management requirements. The farmer does not have the option to negotiate the terms of the agreement, which is offered on a take-it-or-leave-it basis as a condition of the seed purchase.

Farmers can be bound to the terms of the agreement simply by opening and using a bag of seed containing GE seed. Terms of these agreements typically include: direction on where and how to plant the GE seed; prohibition on saving seed; protection of the company's intellectual property rights; requirement to sell the product in specified, approved markets; access for company representatives to fields for inspection to determine contract compliance; and, the resolution of disputes under the contract either through binding arbitration or in a court convenient to the company."

8. Social Issues Related to Genetically Engineered Crops
(see **Appendix 7** for complete references)

Food production in the United States has gone through rapid change over a short period of time leading to increased consolidation of the agriculture industry. The complexity of this issue makes it difficult to assess the cumulative effects of GE crops on society.

Seeds traditionally have been a public good. As such, it has been common practice for farmers to collect and save their seeds for use during the following planting season.[1] Since the U.S. Civil War, however, seeds increasingly have become commodities through two primary routes: 1) technological--via innovations such as hybridization and 2) legal means--by extending patent or patent-like protections to seeds.[2]

The Plant Patent Act of 1930 established patent rights for asexually propagated plants. In 1970, the Plant Variety Protection Act extended patent rights to the developers of new varieties of seed-propagated plants and, in 1985, a legal decision declared that utility patents could be applied to plants. As a result, a utility patent is often sought for products related to GE, and there is no exemption to allow farmers to save seeds or for breeders to develop new varieties based on GE plants.

By the 1990s, when patent-protected genetically engineered crops were first commercialized, many of the large, remaining seed firms were acquired by just six multinational chemical and pharmaceutical companies[3] (See **Appendix 6,** Seed Industry Structure,). A decline in seed companies results in a decline in the choice of seed varieties and other products available to farmers. For example, Seminis eliminated 25% of its entire line of seeds as a cost-cutting measure in 2000.[4] In many areas of the U.S., farmers report seeds for conventional varieties of corn, soy and cotton are extremely difficult to find.[5] Of future concern is that the ability to develop new varieties may be lost if wild relatives of food crops are contaminated with transgenes.[6]

According to Robert Fraley, co-president of Monsanto's agricultural sector, "What you're seeing is not just a consolidation of seed companies; it's really a consolidation of the entire food chain."[7] In 1999, Dr. William Heffernan and his colleagues at the University of Missouri noted that 'food chain clusters' were beginning to form to consolidate control of not just the farm supply sector, but the processing and retail stages of the food system as well.[8] For example, Cargill, which at the time did not have access to genetically engineered crop varieties, sold its international seed division to Monsanto and then entered into a biotechnology joint venture with Monsanto.[9]

Together these firms, like other food chain clusters, have the potential to form a seamless system from the seed to the supermarket shelf, with no changes in ownership or opportunities for competitive markets to influence prices at any stage of production.[10] As one part of the increasing trend toward consolidation, GE reinforces trends toward the centralization of the agricultural supply sector or control of an industry by a few firms.[11]

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1 Herdt 1999
2 Kloppenburg 2005
3 Few other organizations can afford the expensive research needed to develop commercial GE crops. Also note that since this diagram was produced Novartis and Astra-Zeneca merged to form Syngenta, Bayer acquired Aventis, and Monsanto and DuPont formed an alliance to share GE technologies. In addition many more seed companies have been acquired by these 'life science' giants, including the purchase of Seminis by Monsanto in 2005 for $1.4 billion. At the time Seminis was estimated to control 20% of commercial fruit and vegetable seed sales globally, and 40% in the US.
4 Seminis Inc. press release cited in Cropchoice 2000.
5 Center for Food Safety 2005
6 Quist & Chapela 2001
7 *Farm Journal*, October, 1996
8 Heffernan et al. 1999
9 See **Appendix 6** for Cargill/Monsanto Joint Ventures and Strategic Alliances
10 Heffernan et al. 1999
11 Molnar & Kinnucan 1996, Leedham 1996, Heffernan 1999

A direct societal consequence of the increasing trend toward agriculture industry consolidation is the loss of small and mid-scale farms across America. There were nearly seven million farmers in America in the 1930's. That number has decreased to two million, despite a doubling in the U.S. population. "Seventy-five percent of U.S. farm production now comes from only 50,000 farming operations," indicating a growing shift to larger and larger farms.[1]

The decrease in family farms across the U.S. is changing the fabric of rural life. "Between 1987 and 1992, America lost an average of 32,500 farms per year, mostly family farmers. Of those small farmers still on the land, 80% have farm income below the poverty line."[2] Moreover, America's farming communities now suffer some of the highest rates of hunger and poverty in the nation.[3] A number of studies have suggested that communities with many small farms are politically, economically and socially more stable than communities with a few large farms.[4]

One of the leading factors contributing to the shift away from small farms toward larger farms is the high cost of seeds and associated inputs. Previous technological innovations in agriculture that increased production per acre had the effect of putting farmers on a 'treadmill of production.' The treadmill refers to the fact that farmers must constantly adopt new technologies because they soon lead to overproduction and lower prices for commodities (as supply exceeds demand), with gains accruing primarily to the earliest adopters of technologies.[5] The capital-intensive nature of GE crops is one of such innovations likely to increase input costs for farmers[6].

Impacts on Farmers

Choices

Genetically engineered seeds are being tied to other farm products (inputs) to lock farmers into purchasing from the four or five major chemical/GE seed players. For example, Monsanto's Roundup Ready seeds could initially be used only with Roundup herbicide, even though cheaper versions of this herbicide were available. Pioneer DuPont seed gives better interest rates on financing, depending upon how much of 'approved' products and approved chemicals the farmer buys, including those sold by Syngenta, Bayer/Aventis, and Dow.

The precedent set with patented GE seeds is also extended to conventional seeds by 'bundling' chemicals and other farm products for sale to farmers. Syngenta recently began selling a non-GE hybrid barley in the United Kingdom, but only in conjunction with its pesticide. Farmers cannot purchase the barley without also purchasing the chemical.[7]

Other technological innovations such as the Terminator technology and the Traitor technology are being developed with the same goals in mind — to offer a bundled package to farmers and capture a large share of the GE seed market. While 'Terminator' seeds prevent seeds of the parent plant from germinating, 'Traitor' technology requires the application of proprietary chemicals to activate genetic traits.[8]

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[1] Manjula 2000
[2] Ibid
[3] Altieri 2005
[4] Goldschmidt 1946, Lobao 1990, Lyson et a1. 2001
[5] Cochrane 1958, Levins & Cochrane 1986
[6] Benbrook 2002
[7] Howard 2003
[8] Shand 2003

Contracts

Because there are relatively few suppliers of inputs, or buyers of farm products, farmers have little bargaining power when negotiating with these firms.[1] The 'boilerplate' contracts that farmers must sign in order to obtain access to GE seeds typically prohibit saving and replanting seeds, assign to growers the burden of responsibility for preventing contamination (even after the harvest), and contain clauses that allow inspections by biotech company detectives at any time (even years after planting a GE crop).[2]

Monsanto has filed 90 lawsuits to date against US farmers for purported violations of these agreements.[3] (see discussion in **Liability** section**)**

Social Relationships

Contamination of organic or conventional crops with GE varieties, or the introduction of GE weeds, can negatively impact social relationships in farm communities. Since the responsibility for contamination rests with the farmers who grow GE crops, disputes over who is responsible and who will pay the economic costs (loss of premiums, markets, clean-up, etc.) are likely to be felt at the local level. Similar disputes may arise if GE crops lead to increased use of herbicides and neighbors are impacted by chemical drift.[4] Monsanto has set up toll-free numbers to encourage farmers to report anyone they suspect of saving GE seeds, leading to a climate of distrust among neighbors.[5]

Organic farmers threatened with GE contamination face a loss in reputation within organic farming and organic consumer communities. They may also lose access to certain markets and economic relationships and networks.

Impacts for Consumers/Society

Publicly Financed Subsidies for Private Corporations

The public research system helped fund many applications of genetic engineering in agriculture, yet the benefits accrue primarily to the large corporations that commercialize these applications.

For example, Monsanto spent a half a billion dollars each on Roundup resistance and recombinant bovine growth hormone by 1995. Government funding aided the development of Monsanto's rBGH, which was intended to increase the production of milk, despite the fact that the government also funded a program to slaughter dairy cows because of a surplus of milk.[6]

Access to Scientific Information and Independent Scientific Research

The commercialization of genetic engineering has inhibited scientists sharing research results so that they can build on their colleagues' findings. For instance, 48% of public plant breeders surveyed reported difficulty in obtaining genetic stocks for their research and 23% said that this interfered with graduate training.[7] Some key factors in this include a 1980 Supreme Court decision to allow patents on living organisms, *Diamond v Chakrabarty*, and an act of Congress (Bayh-Dole Act) that same year which allowed public universities to profit from the commercialization of research.[8]

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[1] Harl (2000)
[2] Shand 2003
[3] Center for Food Safety 2005
[4] Owen 1998
[5] Weiss 1999
[6] Comstock 1988
[7] Price 1999
[8] Lieberwitz 2005

Pharmaceutical/chemical companies involved in genetic engineering have attempted to prevent publication of studies that have reported potential risks from GE crops. These include Ewen & Pusztai (1999) and Quist & Chapela (2001), as well as books (Lappe & Bailey 1998), magazines (*The Ecologist,* September/October 1998) and television reports (Akre & Wilson 1998).

Another consequence of the influence of financial interests over scientific research is the shifting of academic priorities toward financial interests, rather than the public interest.

For example, Krimsky et al.[1] reported that one out of three scientific journal articles surveyed had an author with a financial stake in the results of their reported research. An earlier study revealed that many of these financial ties were not disclosed.[2] In addition, several universities, including UC Berkeley, have entered into agreements with corporations to receive millions of dollars in funding in exchange for exclusive patent rights on new GE product developments.

This demonstrates a dramatic shift agriculture research funding from an earlier era, where a greater percentage of university funding came from taxpayers. Corporate funding used to be viewed as a contribution to the advancement of science but now is operates more like an investment.[3]

Impacts on Hunger

Proponents of GE crops frequently cite the potential to address the world hunger crisis as a justification for their expanded use.[4] But, GE will not end hunger because hunger is not caused by the lack of ability to grow more food. The world currently produces enough food for everyone on earth to consume a healthy diet. Hunger results from the inability of poor people to buy food and to access the land and resources needed to grow their own food.[5] GE will not help poor farmers grow more food because they simply cannot afford to pay for costly seeds, the required chemicals, or the technology user fees.

[1] 1998
[2] Krimsky et al. 1996
[3] Lieberwitz 2005
[4] Robinson 1999
[5] Altieri, M. A. 2005. The Myth of Coexistence: Why Transgenic Crops are not Compatible with Agroecologically Based Systems of Production., *Bulletin of Science, Technology & Society*, Vol. 25, No. 4: 366.

9. Moral/Ethical/Religious Issues Related to Genetically Engineered Crops

"Decisions about who produces our food, what food is produced, how it is produced, and who gets to eat that food have been steadily moving away from the public realm of households and governments to the more private realm of corporation boardrooms."[1]

Efforts to introduce GE crops are primarily based on commercial interests, rather than social or environmental concerns.[2] Because these technologies are concentrated in the hands of large corporations, an important question to consider is which social groups are most likely to benefit from GE crops, and which groups are most likely to experience loss and risks.[3]

This issue is particularly significant and timely because once a GE organism is released into the environment, it cannot be recalled. Since GE organisms in the environment are self-reproducing they can spread and recombine with other organisms indefinitely.[4]

Below is a discussion of some ethical and moral considerations that arise as a consequence of GE.

Religious/Moral Considerations with Respect to Eating GE Contaminated Food

Since GE foods are not labeled in the US, and GE contamination of non-GE food is possible, foods that are objectionable to certain groups (i.e. animal genes for vegetarians, pork prohibitions, etc.) may be unknowingly consumed. Products of genetic engineering are currently unlabeled in the US, taking away consumers' choice to avoid these products if desired.[5] This contravenes religious or moral freedoms.

Crossing Species Boundaries

Crossing species boundaries has been described by some opponents of GE as "unnatural, immoral and in violation of God's laws".

Ownership of Life

Granting chemical and pharmaceutical companies patents on living organisms and their reproductive processes (even if it is for changing just one of thousands of known genes) increases the economic incentives for fast-tracking gene altering technologies. Such economic pressures may weaken reverence or respect for life.

GE also allows the misappropriation of indigenous knowledge, i.e. patenting plants studied or bred by indigenous peoples for generations, without considering the ethical and moral consequences and obligations.

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1 Hendrickson & James 2005, p. 278
2 Middendorf et al. 1998
3 Robinson, 1999
4 Salyers & Shoemaker 1994; Mariver & Van Aker, 2005.
5 Guthman 2003

10. Other California Legislation

Since March 2004, nineteen California counties have addressed issues of biotechnology, genetically modified organisms, or genetically engineered foods.[1]

Twelve county governments, mainly in the Central Valley, have passed resolutions supporting GE. Several were the result of 3 – 2 votes, others passed unanimously. These resolutions are all worded exactly the same. They affirm the belief that GE is important to the future of agriculture and that it should be regulated exclusively by the federal government.

Six counties have voted on GE issues after citizens garnered the signatures required to have the initiative placed on the ballot. Each of those initiatives undertook to establish a moratorium or ban on the growing of genetically engineered crops in their respective counties, citing concerns about risks to public health and the environment. Of those proposed measures, two were adopted in Mendocino and Marin, and the others were defeated in Butte, Humboldt, San Luis Obispo, and Sonoma counties. Trinity County Supervisors adopted an ordinance limiting GE on a 3-2 vote. Humboldt County citizens are preparing to introduce another ballot initiative to ban GE in 2006.

The San Luis Obispo ballot measure, defeated at the polls, proposed a five year moratorium that could be either lifted or extended by the Board of Supervisors. The Lake County Ordinance (defeated 3-2 by the Supervisors) was limited to genetically-engineered glyphosate-resistant (Round-Up) alfalfa for a 30-month period, renewable by the County Board of Supervisors, with the proviso that a publicly accessible registry of glyphosate-resistant alfalfa field locations would be established for a ten year period after the moratorium expired.

Currently, twelve other California counties, including Santa Cruz, are considering regulations and issues regarding GE foods and food crops.

[1] http://www.ucbiotech.org/resources/legislation/counties.html

Appendix 1

List of Registered Plant-incorporated Protectants

Revised 02/17/06

The registered PIPs are also listed with the rest of the genetically engineered crop plants intended for food or feed that have been reviewed by other US agencies. More information can be found at the website of the United States Regulatory Agencies Unified Biotechnology

Plant-Incorporated Protectant	Registrant	Date Registered	Date Expires
Bt potato Cry 3A	Monsanto 524-474	May, 1995	No Expiration Date
Bt corn event 176 Cry 1Ab	Mycogen 68467-1	August, 1995	April 1, 2001
Bt Corn event 176 Cry 1 Ab (2 products--field corn, popcorn)	Syngenta 66736-1	August, 1995; March, 1998	June 30, 2001
Bt cotton Cry 1Ac	Monsanto 524-478	October, 1995	September 30 2006
Bt corn event MON 801 Cry1Ab	Monsanto 524-492	May, 1996	**Voluntarily cancelled** May 8, 1998
Bt corn 11 Cry Ab (field and sweet corn no refugia for sweet corn)	Syngenta field corn 67979-1 sweet corn 65269-1	August 1996 Febuary 1998	October 15, 2008
Bt corn Cry (Mon 801) 1Ab	Monsanto 524-489	December, 1996	October 15, 2008
Bt corn Cry9C (domestic field corn for feed and non-food uses)	Aventis 264-669	May 1998	**Voluntarily cancelled** October, 2000
Replicase for potato leaf roll	Monsanto 524-474	November, 1998	No expiration date
Bt corn POCry1F	Dow/Mycogen 68467-2	May 2001	October 15, 2008
Bt corn poCry1F	Pioneer/Dupont 29964-3	May 2001	October 15, 2008
Bt cotton Cry2Ab2 in combo with Cry1Ac	Monsanto 524-522	December 2002	September 30, 2006
Bt corn Cry3Bb1	Monsanto 524-528	February, 2003	July 31, 2006
Bt corn stack Cry3Bb1 + Cry1Ab	Monsanto 524-545	October 31, 2003	July 31, 2006
Bt cotton Cry1Ac + Cry1F (WideStrike)	Dow AgroSciences 68467-3	September 30,2004	September 30, 2009
Bt corn MOCry1F Event DAS-06275-8	Dow AgroSciences 68467-4	May 27, 2005	October 15, 2008
Bt corn Cry34Ab1 + Cry35Ab1	Dow AgroSciences 68467-5	August 31, 2005	September 30, 2010
Bt corn Cry34Ab1 + Cr35Ab1	Pioneer/Dupont 29964-4	August 31, 2005	September 30, 2010
Bt corn Cry34Ab1 + Cr35Ab1 with POCry1F	Dow AgroSciences 68467-6	October 27, 2005	October 15, 2008
Bt corn Cry34Ab1 + Cr35Ab1 with POCry1F	Pioneer/Dupont 29964-5	October 27, 2005	October 15, 2008
Bt corn Cry3Bb1 MON8//8017	Monsanto 524-551	December 13, 2005	September 30, 2010
MON88017 + MON 810 AKA Cry3Bb1 + Cry1A	Monsanto 524-552	December 13, 2005	October 15, 2008

Appendix 2

selectable marker:
Promoter: 35S 5' from CaMV
gene: -glucuronidase (uidA) from E. coli
terminator: 35S 3' from CaMV
promoter: 35S 5' from CaMV
gene: neomycin phosphotransferase (nptII) from E. coli Tn5
terminator: 35S 3' from CaMV

c) designation of transformed line: VR327
category: VR
phenotype: PVY resistant
construct: pCP123 and pCP456
genotype: (see descriptions above)

7. Mode of Transformation:
disarmed A. tumefaciens for line VR67;
electroporation for line VR19;
microprojectile bombardment for line VR327

8. Introduction:

Release:
NUMBER OF STATES/TERRITORIES AND SITES: ID(1), ME(1), WI(1)
Russ Burbank's Farm, 1776 Yukon Lane, Taber,
Bingham County, ID, 83221, 1.5 acres;
Pa's Potato Farm, 2004 Chippewa Rd.,
Baker Hill, Hancock County, ME, 04469, 1 acre;
Potato Research Farm, 56 Colby Drive,
Alva Lake, Oneida County, WI, 53777, 1 acre

9. Certification: I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge.
If there are any changes, we will contact APHIS.

Signature _____ Date _____
Name Typed _____

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Appendix 3

Freedom on Information Act Requests and Reponses

-------- Original Message --------
Subject: FOIA Request to APHIS
Date: Thu, 20 Jan 2005 15:55:12 -0800
From: Lisa Bunin <bunin@cruzio.com>
To: foia.officer@aphis.usda.gov

Dear FOIA Officer,

This is a request filed under the Freedom of Information Act.

I request all documents containing information regarding the following topic: all field tests of genetically engineered crops conducted in Santa Clara County, California, during the years 2004 and 2005.

Please include all documents pertaining to the following specific information:

1. name of organism, phenotype, gene, and phenotype category
2. transgenic arthropods and transgenic invertebrates
3. location of the field test, including town and street address
4. amount of acreage on which the test occurred
5. name of company or institute conducting the test
6. results of field tests
7. any notification of pollen spread or other contamination events
8. neighbor inquiries and complaints
9. duration of test
10. procedures followed to ensure that no contamination occurs of future crops being grown on the land where the test was conducted
11. inspection records of APHIS, USDA, and other agencies including dates and times of inspection and name of inspector
12. violations, citations and reprimands
13. status of test and expiration date of permit
14. has the organism in question been deregulated as a result of this test

Thank you in advance for your assistance in this matter.

Sincerely,

Lisa J. Bunin

Lisa J. Bunin, Ph.D.
Environmental Policy Consultant

USDA

ıted States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

Legislative and
Public Affairs

Freedom of
Information

4700 River Road
Unit 50
Riverdale, MD
20737-1232

December 20, 2005

Ms. Lisa J. Bunin
Post Office Box 2306
Santa Cruz, California 95063

Re: FOIA 06-159

Dear Ms. Bunin:

This is to acknowledge receipt of your request received in this Office via the APHIS FOIA Officer website on December 15, 2005, in which you requested to receive "all field tests of genetically engineered crops conducted in Monterey County, California during the years 2004 and 2005.

The records you seek are maintained outside of this Office and we have not yet been able to complete a search to determine whether there are records within the scope of your request. Accordingly, we will be unable to comply with the twenty-working-day time limit in this case, as well as the ten additional days provided by the statute.

I regret the necessity of this delay, but I assure you that your request will be processed as soon as possible. If you have any questions or wish to discuss reformulation or an alternative time frame for the processing of your request, you may contact me at (301) 734-5268.

Sincerely,

Tanya R. Layne

Tanya R. Layne
FOIA Program Specialist

Appendix 4

Current California GE Research on Commercial Food Crops

Food Crops Grown in Santa Cruz County	***Deregulated Commercialized***	***2005 Field Test Release Permits-APHIS #***	***Research and Case Study Stage***
References	www.nbiap.vt.edu	www.isb.vt.edu	www.ncfap.org
Berries			
Blackberries			
Raspberries			Case Study
Strawberries			Case Study
Vegetables			
Broccoli			Case Study
Brussell Sprouts			
Cauliflower			
Celery			
Cucumber			Current Research
Lettuce		05-047-02N, 05-045-22N	Case Study
Onion		06-030-13N	Current Research
Peas		06-030-10N	Research Stage
Pepper			Research Stage
Pumpkin			Research Stage
Squash	Seminis Seed		Case Study
Sweet Corn	Syngenta Seed	many APHIS #s	Case Study
Tomato	Multiple Companies	5 APHIS #s	Case Study
Trees & Vines			
Apple		02-134-04N	Case Study
Avocados			Research Stage
Grapes		04-170-10N, 04-170-09N	Case Study
Kiwi			
Lemons			
Olive			
Peach			
Pear			
Persimmon		8 APHIS #s	Research Stage
Plum			Case Study
Walnut			Research Stage
Ornamentals			
Begonia			Research Stage
Carnation			
Chrysanthemum			Research Stage
Dendrobium			Research Stage
Eucalyptus			Research Stage
Field Grown Flowers		marigold 06-017-07N	
Gladiolus			Research Stage
Indoor Cut Flowers			
Landscape Plants			
Pelargonium			Research Stage
Rhododendron			Research Stage
Rose		05-318-08N, 05-318-07N	Research Stage

www.aphis.usda.gov/brs/status/cata_sta_ca.html (For movement permits, release permits, notifications for CA)
www.usbiotechreg.nbii.gov/database_pub.asp (completed regulatory agency reviews); "Workshop on Biotechnology for Horticulture Crops," Monterey, CA, March 2002

Appendix 5

Other Countries' Requirements for GE Crops and Dates Enacted[1]

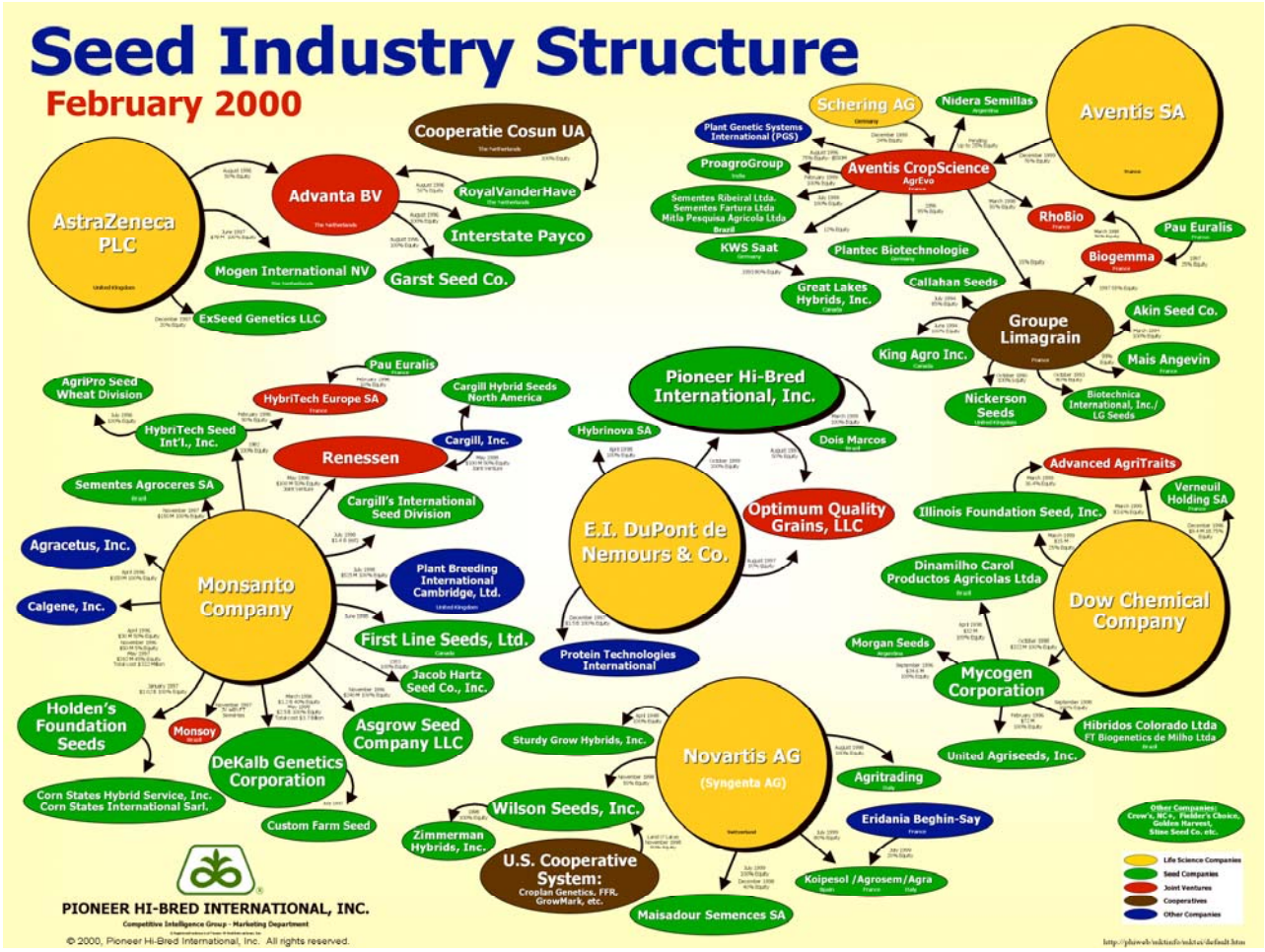
Country	Labeling	Ban or Moratorium on Commercialization	Ban on Imports[2]
Albania		2003	2003
Algeria		2000	2000
Angola			2004
Australia	2001		
Benin		2002	2002
Brazil	2004	1999-2003	1999-2003
Bulgaria	2005	2005	
Cameroon	2003		
Chile	2000		
China	2002		
Costa Rica	1998		
Croatia	2003	2005	
Ecuador	2001		
European Union (currently 25 nations[3])	2004	1998-2004 (de facto)	
Ghana			2005
Hong Kong	2000		
India	2000		
Indonesia	1996		
Japan	2003		
Malawi			2002
Mali	2005		
Mauritius	2004		
Mexico	2003		
Namibia			2002
New Zealand	2001		
Norway	1997		
Paraguay	2000		
Philippines	2001		
Russia	2005		
Saudi Arabia	2001	2001	2001
South Africa	2004		
South Korea	2002		
Sri Lanka			2000-2001
Switzerland		2005	
Taiwan	2001		
Thailand	2002		
Uganda		2002	
Vietnam	2005		
Yugoslavia	2005		
Zambia		2005	2002
Zimbabwe			2002

[1] Data primarily from Center for Food Safety, "Genetically engineered crops and foods: worldwide regulation and prohibition." (October 2005). http://www.centerforfoodsafety.org/pubs/World%20Chart.pdf. For sub-national regulations see http://www.centerforfoodsafety.org/pubs/Regional%20Chart.pdf

[2] Some exceptions are made in specific cases, such as milled grains in some African nations

[3] Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, United Kingdom

Appendix 6



Note that since this diagram was produced Novartis and Astra-Zeneca merged to form Syngenta, Bayer acquired Aventis, and Monsanto and DuPont formed an alliance to share GE technologies.

In addition many more seed companies have been acquired by these 'life science' giants, including the purchase of Seminis by Monsanto in 2005 for $1.4 billion. At the time Seminis was estimated to control 20% of commercial fruit and vegetable seed sales globally, and 40% in the US.

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