REPORT ON GENETICALLY MODIFIED ORGANISMS IN MONTEREY COUNTY, CALIFORNIA

PREPARED BY THE MONTEREY COUNTY AGRICULTURAL COMMISSIONER
In Consultation with the Monterey County Health Department

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PURPOSE

This document addresses some of the key issues relevant to Supervisor Dave Potter's Board referral to evaluate what would be involved to enact a moratorium on Genetically Modified Organisms in Monterey County (letter dated April 14, 2009). This document was developed to provide the Board with a foundational understanding of the range of both regulatory and scientific issues surrounding biotechnology and specifically, crops that have been genetically modified using engineering (GM crops). In addition, this document provides a review of GMO actions considered, evaluated, and undertaken by other counties throughout California. Due to the complexity of both regulatory and scientific understanding of genetically modified organisms (GMOs), this report primarily considers peer reviewed publications that provide analysis, review, or summary of the larger body of primary literature, to the extent possible.

BACKGROUND OF GMOs IN MONTEREY COUNTY

1980's – 1990's: Local Regulation of Genetically Modified Micro-organisms

In the mid-80's Monterey County became one of the initial areas of the country where testing of genetically engineered bacteria were to be field trialed. In November 1985 the EPA, which classified these bacteria as pesticides, granted Advanced Genetic Sciences (AGS) of Oakland, California permission to field test two bacteria (*Pseudomonas syringae* and *Pseudomonas fluorescens* under the trade name of Ice Minus®)[1]; tests were to take place on a small plot of strawberries in the Prunedale area of Monterey County. The Ice Minus® bacteria were to be tested for their ability to prevent strawberry plants from freezing[2]. California Department of Food and Agriculture issued approval of field testing with a state Experimental Use Permit (EUP) on December 12, 1985 for the AGS testing of Ice Minus® bacteria. Testing for Ice Minus® was suspended in March 1986 after the EPA found AGS guilty of testing the bacteria on roof top trees in January 1985, without a permit[3]. This action postponed field testing of Ice Minus® in Monterey County.

This proposed field testing of a genetically modified organism in Monterey County resulted in concern from groups of Monterey county residents living adjacent to the potential test site, a federal lawsuit against the EPA, involvement of various local, state and federal legislators, and an effort to regulate any county field testing through a local ordinance by the Monterey County Environmental Health Officer.

This controversy resulted in the passing of a land use based interim ordinance (#3124—2/11/86) in Monterey County prohibiting field testing of genetically modified microorganisms (GMMO). The original interim ordinance (#3124) was strongly opposed by the majority of agricultural trade associations and California Department of Food and Agriculture. CDFA questioned the ordinance based on preeminence of jurisdiction by federal (EPA) and state (CDFA) governance over biopesticides. The original interim ordinance was supported by a small group of north county neighbors residing close to the proposed test site, attorney Jeremy Rifkin, a letter from a

[1] New Scientist (April 3, 1986). Rooftop gene test was illegal.
[2] Barinaga, Marcia. (April 1987). Field Test of Ice-Minus Bacteria Goes Ahead Despite Vandals. *Nature* **327**(819). Accessed November 29, 2010 at http://www.nature.com.oca.ucsc.edu/nature/journal/v326/n6116/pdf/326819b0.pdf
[3] USDA-APHIS Biotechnology Regulatory History accessed on September 3, 2010 at http://www.aphis.usda.gov/biotechnology/about_history.shtml.

European Parliament body, and ultimately garnered significant interest from others within and outside the county.

A second permanent ordinance (#3132—3/28/86) was passed by the Board to extend and make permanent the ban on the experimental release of genetically modified microorganisms in Monterey County. In May of 1987, the Monterey County Board of Supervisors passed an ordinance (#3233) that changed the regulation for location and siting of GMMO experiments in Monterey County to allow it with a use permit on agriculturally-zoned properties. There were also further restrictions within one mile of occupied structures.

In November of 1995 the Board of Supervisors adopted an amendment of Title 20 & 21 with an ordinance (#3849) that relaxed the requirements for allowing GMMO testing. It made such experiments an allowed use on agriculturally-zoned properties, with approval from the Monterey County Agricultural Commissioner. Now a use permit is required only if there is an occupied residence within 100 feet of the site. A CEQA environmental review is also required. A permit committee was established comprised of the Director of Environmental Health, County Agricultural Commissioner, and the Director of Planning. (Current County Codes 20.64.140 and 21.64.140 – Appendix 1). To date, no permits have been applied for or issued.

According to many leading biotechnology and food safety researchers, the existence of an anti-biotech ordinance in Monterey County has dissuaded researchers from conducting biotechnology research in the county.

2000's: Consideration of Local Regulation of GMOs

In 2004, in response to concerns from diverse sectors of the community, the Monterey County Agricultural Advisory Committee (AAC) reviewed the issue of GMOs and considered bringing forward a resolution supporting biotechnology to the Board of Supervisors. For various reasons including the controversy and complexity of this issue, the AAC elected not to pursue a resolution in support of biotechnology at that time.

In early 2008, based upon constituent questions regarding GMOs and the potential establishment of a moratorium on GM crops, Monterey County Supervisor Dave Potter made an informal referral of the issue to the Agricultural Advisory Committee. The AAC took up the issue several times, hearing diverse and opposing views. Based upon the recommendation of the AAC, rather than considering a resolution or ordinance, the Board of Supervisors (via the Legislative Committee) recommended a support position on AB 541[4]. AB 541 was designed to protect growers with crops contaminated with *de minimus* amounts of GM material from patent-holder lawsuits and also enacts sampling protocols and procedures. AB 541 was the first successful legislative effort addressing GMOs and was chaptered into law in September 2008.

On April 14, 2009, again in response to citizen concerns, Supervisor Potter made a board referral related to considering a moratorium on the growth and cultivation of GMOs in Monterey County (Appendix 2). In this referral, Supervisor Potter requested that the Agricultural Commissioner and the Director of Environmental Health provide a response outlining procedural options for the

[4] California Assembly Bill Analysis of AB 541 accessed on September 11, 2010 at http://www.leginfo.ca.gov/pub/07-08/bill/asm/ab_0501-0550/ab_541_cfa_20080825_114503_sen_floor.html

County to consider in adopting a moratorium on GMOs, similar to what was passed in the County of Santa Cruz in 2006. In addition, the referral requested an assessment of concerns surrounding a moratorium, including: potential health impacts of GMOs, consideration and balance of diverse interests throughout the County, the tools, resources and staff time required for the development of an ordinance, and an analysis of whether such an ordinance is appropriate at the County level, or better addressed at the State or Federal level. This report is intended to provide information on the range of issues surrounding GMOs for the Agricultural Commissioner, the Director of Environmental Health and the Board of Supervisors to consider in response to the referral.

INTRODUCTION TO GMOs

History and Evolution of Plant Breeding Techniques

Plant breeding[5] has been practiced for thousands of years and the technology of classical breeding techniques has evolved considerably in modern applications. Classical plant breeding uses deliberate interbreeding (crossing) of closely or distantly related but compatible individuals to produce new crop varieties or lines with desirable properties. Plants are crossbred to introduce traits from one variety or line into a new genetic background. Classical breeding relies largely on recombination between similar molecules of DNA (chromosomes) to generate genetic diversity. Following World War II a number of techniques were developed that allowed plant breeders to hybridize somewhat more distantly related species and artificially induce genetic diversity. For example, the cereal triticale is a wheat and rye hybrid. Since then, classical plant breeders may make use of a number of in vitro techniques such as protoplast fusion, embryo rescue or mutagenesis to generate diversity and produce hybridized plants that would not exist in nature.

Marker assisted selection or marker aided selection (MAS)[6] is a more efficient selection system that bridges classical breeding and genetic engineering techniques. With MAS, a marker is used for indirect selection of a genetic determinant(s) of a trait of interest. These markers can be morphological, biochemical or based on DNA/RNA variation. MAS can be useful for traits that are difficult to measure, exhibit low heritability, and/or are expressed late in development. To avoid problems specific to morphological markers, DNA-based markers have been developed. Numerous markers have been mapped to different chromosomes in several crops including rice, wheat, maize, soybean and several others. Those markers have been used in diversity analysis, parentage detection, DNA fingerprinting, and prediction of hybrid performance. Molecular markers are useful in indirect selection processes, enabling manual selection of individuals for further propagation.

Modern plant breeding uses techniques of molecular biology to select, or in the case of genetic engineering, to insert, desirable traits into plants. Genetic modification of plants via engineering is achieved by adding a specific gene or genes to a plant, or by down-regulating a gene to produce a desirable phenotype. Adding or down-regulating a gene is done by the application of

[5] The history of plant breeding was accessed on November 29, 2010 at http://cls.casa.colostate.edu/transgeniccrops/history.html

[6] Definition of Marker Assisted Selection was accessed on November 29, 2010 at http://www.healthobservatory.org/library.cfm?refID=88241

recombinant DNA technologies; recombinant DNA (rDNA) is a form of artificial DNA that is created by combining two or more sequences that would not normally occur together[7]. A genetically modified organism (GMO) or genetically engineered organism (GEO) is an organism whose genetic material has been altered using genetic engineering techniques. These techniques, generally known as recombinant DNA technology, use DNA molecules from different sources, which are combined into one molecule to create a new set of genes[8]. The plants resulting from adding or turning off a gene are often referred to as transgenic plants. Genetic engineering can produce a modified plant with the desired trait or traits faster than classical breeding because the majority of the plant's genome is not altered.

Both classical breeding and genetic engineering allow modification of genetic information in a cell. Genetic engineering methods allow for the handling of single genes, whereas classical breeding methods involve the exchange or rearrangement of thousands of genes[9]. Genetic engineering can produce a modified plant with a desired trait or traits that otherwise may not be possible with classical breeding. Some of the uses and products derived from genetic engineering include pharmaceutical and medical applications, specialty enzymes for food production from GM microbes, and GM crops used for food and fiber production. Genetic engineering started in the San Francisco Bay Area in 1973 and California, especially northern California, has been a world leader in biotechnology since[10].

Evaluating Risk: Process versus Product

A 2002 National Research Council (NRC) committee report[11] agrees with the 2000 NRC findings that both transgenic and conventional approaches (e.g. hybridization, mutagenesis) for adding genetic variation to crops can result in unintended effects on crop traits. The NRC committee found that it is the final product of a given modification, rather than the modification method or process, which is more likely to result in unintended adverse effects. However, the NRC committee findings in 2002 also agree with prior findings (1989, 2000) that there are "no new categories of risk associated with transgenic [GM] plants".

Though both transgenic and conventional techniques used to create genetic variation present risks of unintended effects on crop traits, this document limits its discussion to genetically modified organisms (GMOs). Specifically, this report addresses GM crops.

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[7] Definition of Recombinant DNA: Jeremy M. Berg; John L. Tymoczko; Lubert Stryer (2007). *Biochemistry*. San Francisco: W. H. Freeman. ISBN 0-7167-8724-5), accessed on September 11, 2010 at http://en.wikipedia.org/wiki/Recombinant_DNA:

[8] Definition of Genetically Engineered Organism accessed on November 29, 2010 at http://www.ornl.gov/sci/techresources/Human_Genome/elsi/gmfood.shtml

[9] Lemaux, P. Introduction to Genetic Modification. University of California. Publication 8178.

[10] Koehler, G.A. (April 1996). Bioindustry: A Description of California's Bioindustry and Summary of Public Issues Affecting its Development. California Research Bureau. Sacramento, CA. Accessed on September 11, 2010 at http://www.library.ca.gov/CRB/96/07/

[11] National Research Council (2002). Environmental Effects of Transgenic Plants: The scope and adequacy of regulation. National Academy Press, Washington, D.C.

Current Status of Commercial Biotech Crops

According to the 2009 International Service for the Acquisition of Agri-Biotech Applications (ISAAA) brief *Global Status of Commercialized Biotech/GM Crops: 2009*[12], a total of 331 million acres of biotech crops were planted worldwide in 2009, an increase of 7% from the previous year. Soybeans accounted for the largest share (52%), followed by corn (31%), cotton (12%), canola (5%), and modest amounts of papaya, squash, alfalfa, sugar beet, tomato, poplar, and sweet pepper. The brief reported that 62% of all biotech varieties planted in 2009 were herbicide resistant crops. Drought tolerant GM corn is under development and is anticipated for commercial launching in the US in 2012. In 2007 biotech crop plantings in the United States accounted for 50% of the global total[13]. In 2009 the US global share was just less than 48% due to increased plantings in 24 other developed and developing countries.

REGULATORY FRAMEWORK

Federal

In the 1980's the Federal government began to formally regulate genetically modified organisms (GMOs). As iterated above, NRC committee findings in 1989, 2000, and 2002 found that there are "no new categories of risk associated with transgenic plants"[14]. In 2000 and 2002 NRC committee reports also found that both transgenic and conventional approaches (e.g. hybridization, mutagenesis) for adding genetic variation to crops can cause changes in the plant genome that result in unintended effects on crop traits.

In the mid-1980's, the U.S. Coordinated Framework for the Regulation of Biotechnology[15] was developed. This framework calls on three U.S. agencies to work together in assessing the safety of the process and products of genetic engineering: the U.S. Department of Agriculture (USDA), U.S. Food and Drug Administration (FDA), and the U.S. Environmental Protection Agency (EPA).

The USDA has the lead role and the department's Animal and Plant Health Inspection Service (APHIS) has developed a system that addresses agricultural and environmental safety of GM plants and animals. It reviews petitions to grow GM crops to determine if they are "plant pests" and issues field trial permits for experimental GM crops. Once the USDA has deregulated a GM crop it has no further or on-going regulatory authority over them. The FDA addresses food and feed safety utilizing a system of voluntary consultation for biotech developers. The EPA addresses food safety and environmental issues with new pesticides and uses of plants with altered pesticide properties. All three federal agencies that oversee GM crops have legal rights to

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[12] James, C. (2009). Global Status of Commercialized Biotech/GM Crops: 2009. ISAAA Brief No. 41. ISAAA: Ithaca, NY.

[13] Brooks, G. and P. Barfoot (May 2009). GM Crops: Global Socio-Economic and Environmental Impacts 1996-2007. PG Economics Ltd, Dorchester, UK.

[14] National Research Council (2002). Environmental Effects of Transgenic Plants: The scope and adequacy of regulation. National Academy Press, Washington, D.C.

[15] U.S. Office of Science and Technology (1986). U.S. Coordinated Framework for Regulation of Biotechnology. Accessed on September 11, 2010 at http://usbiotechreg.nbii.gov/CoordinatedFrameworkForRegulationOfBiotechnology1986.pdf

demand immediate market removal of any product if valid scientific data show safety concerns for consumers or the environment.

The USDA and FDA also have specific regulatory authority over GM crops developed to produce pharmaceutical products[16]. No GM pharmaceutical crops have been declared as non-regulated by USDA-APHIS. According to the Congressional Research Service, APHIS officials state they 'cannot envision deregulating pharmaceutical plants' and thus in commercialization pharma-crops are intended to grow under both APHIS permit and FDA regulation.

Concerns have been identified regarding the process in place to regulate, evaluate and monitor GM crops; the process is continually evolving to address scientific, market and societal needs. A 2000 National Research Council study of the coordinated framework for regulating GM plants, particularly those engineered to resist pests, concluded that the framework had been operating effectively for over a decade yet it recommended several kinds of improvements that would be helpful in the face of a larger number of commercialized GM pest-protected plants[17]. In 2002 the National Research Council conducted a study of the adequacy of APHIS to regulate effectively to safeguard against negative environmental effects of GM plants[18]. In addition to general regulatory improvement recommendations, the NRC studies provide a very specific approach to a scientific research and monitoring program to help address deficiencies in the regulatory process.

A more recent report from the Government Accountability Office on genetically engineered crops identified three key areas for improvement to the federal agency coordinated regulatory framework[19]. These recommendations were:

1. FDA make public the results of its early food safety assessments of GM crops;
2. USDA and FDA develop an agreement to share information on GM crops with traits that, if released into the food or feed supply, could cause health concerns; and
3. USDA, EPA and FDA develop a risk-based strategy for monitoring the widespread use of marketed GM crops.

The agencies agreed in part with all three recommendations.

On October 9, 2008, APHIS published in the Federal Register (73 FR 60007-60048, Docket No. PHIS-2008-0023) a proposal to revise its regulations regarding genetically engineered organisms. On January 16, 2009, APHIS reopened the public comment period for 60 days regarding its proposed rule changes (Federal Register 74 FR 2907—2909, Docket No. APHIS-2008-0023). APHIS held a scoping session in April 2009 to allow discussion of issues raised during the public comment period as well as an extension of the public comment period to June (Federal Register 74 FR 10517-10518, Docket No. APHIS-2008-0023). APHIS's opening of its

[16] Congressional Research Service (2005). Regulation of Plant-Based Pharmaceuticals. CRS Report for Congress, Order Code RS21418. Library of Congress, Washington, D.C.

[17] National Research Council (2000). Genetically Modified Pest-Protected Plants: Science and Regulation. National Academy Press, Washington, D.C.

[18] NRC (2002). Environmental Effects of Transgenic Plants: The scope and adequacy of regulation.

[19] United States Government Accountability Office (November 2008). Genetically Engineered Crops: Agencies are Proposing Changes to Improve Oversight, but Could Take Additional Steps to Enhance Coordination and Monitoring. Publication GAO-09-60, a report to the Committee on Agriculture, Nutrition, and Forestry, U.S. Senate.

proposed rule revisions provided the general public an opportunity to participate in an open dialogue and exert some influence over the federal regulation of GM crops. APHIS received more than 5,000 public comments on their proposed rule changes[20].

State of California

According to a 2004 report exploring state and federal roles in the oversight of genetically modified crops titled *Tending the Fields*[21], most state government officials and many stakeholders surveyed say that the primary responsibility for human health and environmental protection should rest at the federal level. In fact, the report found that many feel that states lack the resources and specialized expertise to duplicate what APHIS, EPA and FDA do, and that it is best for states to rely on federal decisions. Findings of the California Council on Science and Technology (2002) [22] support this statement. States do not appear to be developing duplicative scientific review capacities and regulatory processes to address the core food and environmental safety issues posed by biotech crops. States generally seek a collaborative relationship with federal agencies, preferring an active role in both initial approval decisions and compliance oversight when decisions have implications for local agricultural producers. States also hold the common sentiment that state-level involvement in biotechnology regulation is necessary and important to adequately address local concerns, specifically related to the welfare of local agricultural producers (e.g. market access, crop plant health) and other economic interests of the state.

The California Department of Food & Agriculture (CDFA) concurs[23] with the findings above, and emphasizes the position that regulation and oversight of GMOs is a federal issue (as opposed to state) and that the best available science should be used when discussing GMOs. The state's regulatory and statutory role in regulating GMOs is limited to reviewing research permits for compliance with California quarantine regulations, use of organisms that might require a permit, and evaluating the potential for a GMO plant to become weedy. Prior to issuance of federal permits to conduct GMO research (and transport) in California, CDFA's Permits Unit has a seven to ten day period to respond and comment, depending upon type of permit. Once a GMO has been deregulated by the federal government, the state has no further role. CDFA has no current outlook for change in the state's role in GMO regulation.

In 2008 AB 541 (Huffman, D-Marin/Sonoma) became law in California[24]. This legislation indemnifies California's farmers who experience drift of GM pollen or seed onto their land and subsequent contamination of non-GM crops; it is designed to protect growers with crops contaminated with *de minimus* amounts of GM material from patent-holder lawsuits. The legislation was broadly supported by diverse interest groups; locally, the Monterey County Board of Supervisors supported this bill.

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[20] Search results for public comments on AHPIS-2008-0023 accessed April 2010 at http://www.regulations.gov/

[21] Taylor, M. *et al.* (December 2004). Tending the Fields: State and Federal Roles in the Oversight of Genetically Modified Crops. Pew Initiative on Food and Biotechnology.

[22] California Council on Science and Technology (June 2002). Benefits and Risks of Food Biotechnology. Sacramento, California.

[23] Personal communication with Robert Leavitt, Director of Plant Health Services (CDFA) on August 6, 2010 and September 2, 2010.

[24] Assembly Bill Status of AB 541. Accessed on September 11, 2010 at http://www.leginfo.ca.gov/pub/07-08/bill/asm/ab_0501-0550/ab_541_bill_20080930_status.html

There have been efforts at the state level to limit local action on GMOs in an effort to improve statewide coordination and prevent a patchwork of regulation throughout California. For example, in 2006 SB 1056 (Florez, D-Shafter) was being considered by the state legislature. SB 1056 proposed that provisions of law related to nursery stock and seed are of statewide concern and occupy the entire field of regulation, including the registration, labeling, sale, storage, transportation, distribution, notification and use of nursery seed and stock, to the exclusion of local regulations. This bill moved out of committee in November 2006 but was not chaptered into law. It was supported by the California Agricultural Commissioner and Sealers Association[25].

Local Jurisdictions

Just over half of the counties in California have taken or considered taking action either in favor of or against GMOs over the past decade (See Figure 2). As of October 2008[26], county voters and/or Boards of Supervisors throughout California had taken the following actions: Four (4) counties voted on and passed anti-GMO ordinances; four (4) voted on and rejected anti-GMO ordinances; ten (10) previously considered anti-GMO ordinances (and no action was taken); two (2), including Monterey County, are currently considering anti-GMO ordinances; and twelve (12) passed pro-GMO resolutions. The process by which individual counties have approached GM crops is varied. The County Supervisors' Association of California passed a resolution in support of life sciences and its contributions to world health and agricultural improvements on June 2, 2005; the resolution is included as Appendix 12. What follows is a representative sample of case studies showing how different counties have addressed GMOs.

Case Study: Mendocino County
(2004: Voters Approve Ban of Genetically Modified Organisms: County Ordinance Chapter 10A.15)

In March 2004, Mendocino County became the first county nationwide to pass a ban on the growth and propagation of genetically modified plants and animals[27]. The initiative, Measure H, passed with 56% of the vote and anti-GMO debate seemed to center most squarely on the theme of limiting multinational corporate influence in local agricultural policy[28,29]. According to Walsh-Dilley's case study of Mendocino's ban on GMOs, this small community's ordinance became important at a state, national and even international level for both sides of the biotechnology debate. Proponents of the initiative argued that potential losses to organic agriculture in the County associated with the risk of genetic contamination were particularly high; one-third of the County agriculture is organic. Proponents further argued that U.S. regulators do not adequately regulate genetically engineered food crops and that the safety of human health and the environment cannot be assured.

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[25] Senate Bill Analysis of SB 1056. Accessed on September 11, 2010 at http://www.leginfo.ca.gov/pub/05-06/bill/sen/sb_1051-1100/sb_1056_cfa_20060825_102424_sen_floor.html

[26] University of California (October 2008). Map of California Counties Ordinances. Accessed on September 11, 2010 at http://ucbiotech.org/resources/legislation/legislation.html

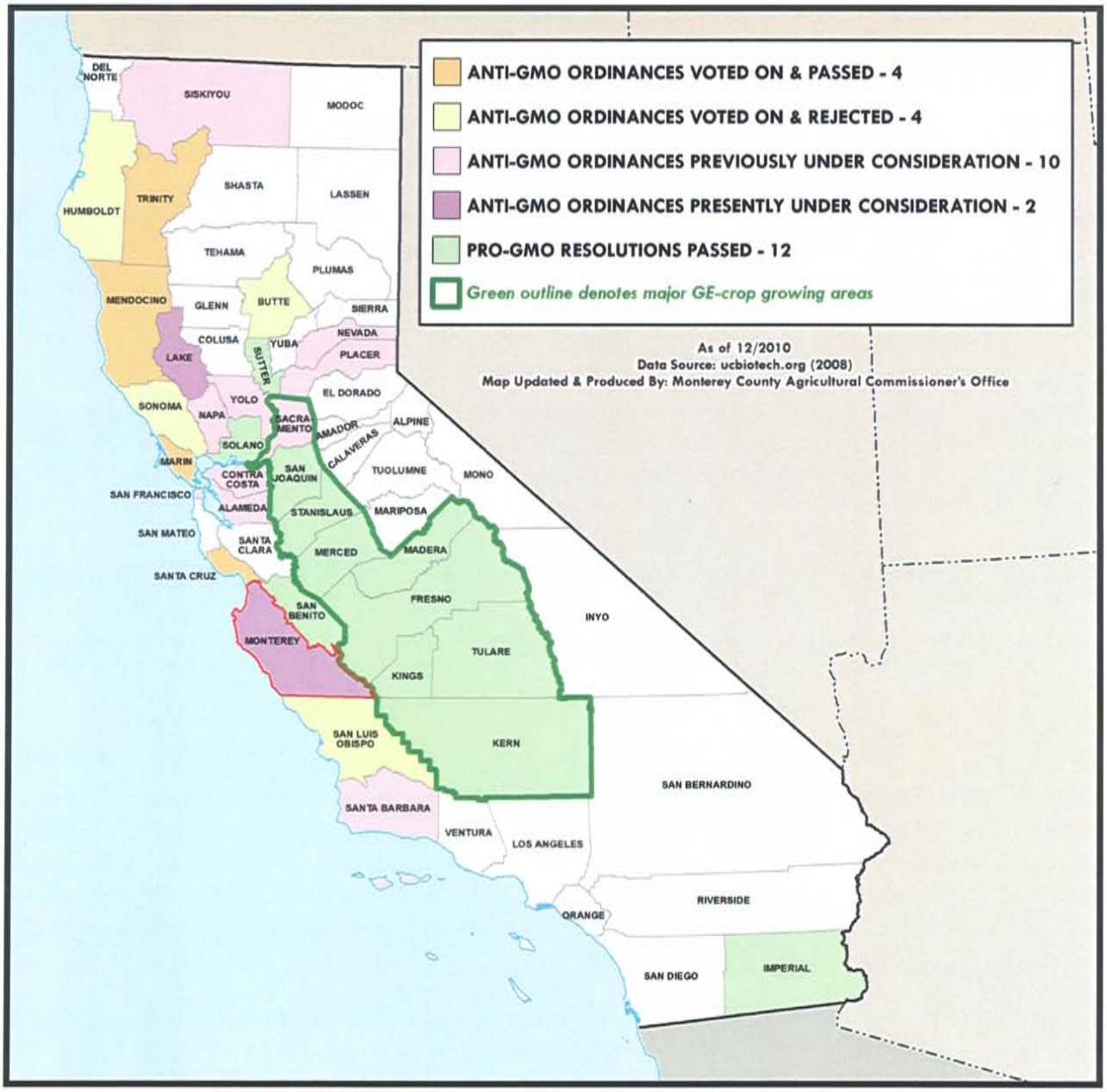
[27] Meadows, R. (2004). California Voters Assess Anti-GMO Initiatives. *California Agriculture* 58(4):182-183.

[28] Walsh-Dilley, M. (2009). Localizing Control: Mendocino County and the Ban on GMOs. *Agric Hum Values* 26:95-105.

[29] Meadows, R. (2004). California Voters Assess Anti-GMO Initiatives.

This effort established Mendocino County Code, Title 10A, Agriculture, Chapter 15 Prohibition on the Propagation, Cultivation, Raising and Growing of Genetically Modified Organisms in Mendocino County (Appendix 3). The code specifically excludes "organisms created by traditional breeding or hybridization, and microorganisms created by moving genes or gene segments between unrelated bacteria."

FIGURE 2: California Local GMO Activities (www.ucbiotech.org 10/2008)



Case Study: San Luis Obispo County
(2004-present: Anti-GMO Ordinance efforts evolved to Co-Existence Methods Table)

San Luis Obispo County's (SLO) efforts to address the growing and cultivation of GM crops within the county formally began in 2004 when the county was included in a "protocol for production of genetically modified rice" by the California Rice Commission. By July the SLO Board of Supervisors received an initiative petition to establish a county ordinance prohibiting the growing of GMOs in the county. This initiative appeared and was defeated (54% to 46%) as Measure Q on the November 2, 2004 ballot.

Following the defeat of Measure Q, the SLO BOS decided not to pursue a ban on GM crops but rather provide educational forums addressing GM Foods and GM Crops separately. According to Bob Lilley, San Luis Obispo Agricultural Commissioner[30], this 12-15 member GM Crop Committee formed in April 2005 and met 11 times through July 2006. During this time the committee conducted significant fact finding efforts, technically supported by the University of California. This committee then looked at a local plan to mitigate GMOs in the county and it developed a Co-existence Table as the foundation of a good neighbor policy for growing GMOs. According to Mr. Lilley, there was some interest in making the voluntary co-existence/good neighbor policy into a regulatory requirement and/or establishing a notification system for GMOs grown in the county. However, arguments against this further formal action raised concerns about confidentiality and possible federal pre-emption on regulating GMOs.

On August 22, 2006 the GM Crop Committee presented its findings and proposed Co-Existence Methods Tables to the SLO Board of Supervisors. The Co-Existence Methods Table (Appendix 4) was to be circulated with the agricultural industry and was accepted and filed by the Board of Supervisors but at the time of writing this report, is not yet formally adopted by the County.

The GMO Foods committee also met during this time frame, and on August 14, 2006 presented to the Health Commission its report looking at the health effects of GM crops on San Luis Obispo. Ultimately the committee recommended food labeling for GMO materials, however according to Mr. Lilley, this recommendation for local labeling was not pursued as it is pre-empted by federal commerce rules. There has been no local GMO activity since 2006.

Case Study: Santa Cruz County
(2005-2006 Developed Genetically Engineered Crop Moratorium: County Ordinance Chapter 7.31)

In June 2005 the Santa Cruz County Board of Supervisors created a subcommittee of the Public Health Commission to advise on the use of genetically modified crops within the county. By June 2006 the subcommittee presented the SC County Board of Supervisors with a Report of Genetically Engineered Food Crops in Santa Cruz County dated May 24, 2006 (Appendix 5). The Board voted unanimously to establish a Moratorium that would prohibit the planting and production of GM crops in SC County. This effort established Santa Cruz County Code, Title 7, Health and Safety, Chapter 7.31 Genetically Engineered Crop Moratorium (Appendix 6).

[30] Personal communication with Bob Lilley, SLO County Agricultural Commissioner on August 11, 2010 and September 2, 2010.

The Santa Cruz Ordinance cites that the following issues surrounding GM crops necessitate a GM crop moratorium: 1) inadequate regulatory monitoring, oversight, and public disclosure of planting locations of GM crops; 2) lack of comprehensive safety testing of GM crops; C) lack of legal recourse for farmers/gardeners should their crops be contaminated by GM material; D) absence of labeling requirement for GM seeds or rootstocks; E) inadequate safeguards to prevent environmental contamination from GM crops and insufficient knowledge of the consequences to ecosystems. To date there have been no complaints or investigations of GMO activity in Santa Cruz County. The Ordinance notes several factors that the board of supervisors may consider in reevaluating the on-going need for the ordinance; please refer to Appendix 6 for more details.

The committee's June 2006 report recommendation, which was approved by majority vote, supported the ban on the planting and production of GM crops within the county. Four (4) of the 12 member committee, however, did not support this ban[31] and prepared a Minority Report on Response to the Board of Supervisors (Appendix 7). The subcommittee voted and agreed (by majority) that the minority letter would not be included in the final report; it was presented to board as a separate attachment to the Board packet. The minority opinion letter noted that there was not supporting evidence to justify regulatory intervention at the local level. In addition, the minority opinion believed that the technology holds promise to potentially benefit local agriculture and the environment.

Prior to the recent effort, the SC BOS had unanimously approved the 1988 Santa Cruz County Code, Title 7, Health and Safety, Chapter 7.30, "Noticing Requirements, Indemnification and Financial Assurances for the use of Recombinant DNA technology" (Appendix 8). This ordinance requires that anyone making use of rDNA technology within the unincorporated portions of the county must: 1) notify the County Health Officer and the Clerk of the Board of Supervisors of the County of Santa Cruz of the activity; 2) indemnify and hold harmless the County from actions or claims brought on account of any injury or damage resulting from the rDNA activity; and 3) provide financial assurances that are adequate to respond to damage claims arising from such use. Exempt rDNA technology uses include the use of any "economic poison" and rDNA technology duly given final approval and certified by the Federal and/or California State Governments.

Case Study: Lake County
(2005- Present: Anti-GMO Ordinance efforts evolved to GM Crop Registration Ordinance Under Development)

In 2005 the Lake County Board of Supervisors voted down (3-2) a proposed ordinance that would have placed a 30-month moratorium on GM alfalfa. In October 2008, after turnover of one Supervisor, the Lake County Board of Supervisors initially approved (3-2) an ordinance to ban the use of GM crops within the county. In response to that Board decision, the GM Crops Advisory Committee was formed in January 2009 and met various times throughout that year. The committee developed a report to the Board of Supervisors that identified a series of gaps in the regulatory process as well as other concerns associated with economic, environmental, and social impacts of GM crops in the county (Appendix 9). By the end of 2009, however, the committee was unable to achieve unanimous consensus on recommendations to the board for the

[31] Personal communication with Dave Moeller, former SC County Agricultural Commissioner on August 20, 2010 and September 8, 2010.

anti-GM crop ordinance. It was reported that this failed effort of the committee to gain consensus was primarily the result of the size of the committee, significantly divergent views of some committee members, and the need for unanimity[32].

In response to the committee's failure to reach consensus, the Lake County Board of Supervisors agreed in December 2009 to reduce the GM Crop Advisory Committee membership to 7. In early February 2010, the seven member committee developed a middle ground approach proposal that was unanimously accepted by the Board of Supervisors to be used as the basis for an ordinance to regulate GM crops in Lake County (Appendix 10). According to Chuck March[33], Lake County Farm Bureau Executive Director, one grower in the county had been producing GM maize for 3 years. Reportedly, the current cultivation of GM crops along with the County Right to Farm Ordinance limited the Board of Supervisor's ability to call GMOs a nuisance and certify the county as GM Free, creating a significant barrier to completely banning GMOs in the county.

The Advisory Committee's recommendations currently being considered for the Lake County ordinance include the following components: 1) Commercial GM crops to be registered with the California Crop Improvement Association (CCIA) or Agricultural Commissioner's Office; 2) A GM Advisory Committee to be established to advise the Agricultural Commissioner; 3) Agricultural Commissioner to compile and maintain list of all GM crops commercially available or undergoing evaluation; 4) Agricultural Commissioner to establish scientifically based GM crop growing guidelines to prevent gene flow (*de minimus* levels of incidental contamination were recommended, but consensus was not reached); 5) Registrants information to include location and planting date of GM crop and registrant must certify adherence to GM crop guidelines; 6) Overhead costs to be borne by County of Lake; 7) Registrar to conduct compliance audits and if out of compliance, Agricultural Commissioner to exercise powers for abatement procedures under Chapter 6 [Section 5401-5405] of the California Food and Agriculture Code; 8) Upon request, registrar will advise if specified GM is planted within 2 mile radius and the exact location is not to be made publicly available; 9) registration process may be revisited no later than five years from date of establishment.

The current proposal is being used by County Counsel to develop the ordinance language while the County Agricultural Commissioner's Office is estimating the costs to implement and run the program. It is important to note that the Agricultural Commissioner's powers for abatement under California Food and Agriculture Code Chapter 6 [Section 5401-5405] applies to pest species, yet when deregulating a GM crop, the USDA makes the determination that said crop is *not* a plant pest. Chuck March originally suggested Lake County consider the Agricultural Commissioner powers for abatement under this Food and Agriculture Code; however, he notes that there has been no legal review to determine its applicability in this circumstance.

At the time of publication of this report, Lake County is in the process of developing draft language for an ordinance that may be considered at a later date by the Board of Supervisors.

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[32] Larson, E. (February 9, 2010). Board approves GE crop registration proposal; document to form basis of new ordinance. Lake County News.

[33] Personal communication with Chuck March, Lake County Farm Bureau Executive Director on August 23, 2010.

Case Study: Stanislaus County
(2005 Resolution in Support of the Use of Biotechnology in the Agricultural Industry)
In 2005, the Stanislaus County Board of Supervisors adopted a resolution in support of the use of biotechnology in agriculture. Eleven other counties, nearly all Central Valley counties, adopted similar resolutions in support of agricultural biotechnology. This resolution was adopted in response to both voter and Board of Supervisor activities in counties throughout California to prohibit or limit the use of biotechnology. In order to protect agriculture and to affirm the rights of growers to choose to utilize the widest range of technologies available, several San Joaquin Valley counties adopted resolutions to protect this right. The Stanislaus Board of Supervisors unanimously approved this resolution citing the following reasons summarized from the resolution (See Appendix 11): 1) To affirm the right of farmers and ranchers to utilize the widest range of technologies available to produce a safe, healthy, abundant and affordable food supply; 2) Agricultural biotechnology holds the potential to improve agricultural and environmental sustainability; 3) Genetically engineered crops have been regulated by the federal government for nearly two decades and go through an extensive multi-year testing process prior to being approved to be grown on a commercial basis; and 4) GM crops are the most highly regulated and scrutinized food in the world.

CONSIDERING THE BENEFITS AND CONCERNS OF GM CROPS

Agriculture and Biotechnology

Agricultural biotechnology of the past few decades has shown promising benefits for increasing food and fiber production for a burgeoning world population, reducing pesticide use, improving food quality, and providing new pharmaceuticals and bio-fuels for the future[34].

The history of the development and market approval of GM papaya with ringspot virus resistance has often been regarded as a model for showing the timely and successful use of biotechnology in agriculture. As described by Dennis Gonsalves in *The Papaya Story*[35], the papaya ringspot virus (PRSV) was discovered in 1992 in the Puna district of Hawaii Island, where 95% of the state of Hawaii's papaya was being grown. By 1994, PRSV was widespread and causing large losses to papaya production in the Puna district. Meanwhile, genetically engineered papaya was produced and shown to be resistant to the virus in 1991. Thus, a concerted effort was made by the researchers to characterize, deregulate, and commercialize the transgenic papaya. The papaya was released to growers in 1998 and stemmed the destruction being caused by PRSV. According to the author, the key factors that contributed to its success were the starting of the research before PRSV became a severe problem in Puna, the commitment of the researchers to bring the project to a practical end, and the close communication and collaboration between the industry and the researchers.

Contamination of non-GM crops or wild plants with GM materials poses a potential concern. Gene flow is possible when compatible plants are nearby; GM traits can move from a flowering

[34] CCST (June 2002). Benefits and Risks of Food Biotechnology.
[35] Gonsalves, D. 2003. The papaya story: a special case or can it be generic?. In: Eaglesham, A., Hardy, Ristow, S., editors. Science & Society at a Crossroad, National Agricultural Biotechnology Council Report 15, June 1-3, 2003, Seattle, Washington. p. 223-233.

plant and persist in unintended (compatible) plants (for example, a GM crop pollen transfer to compatible non-GM crops, weedy species or home garden plantings). GM varieties can also persist in the agricultural environment[36]. At modest acreages those concerns are not significantly greater for transgenic crops than those posed by most crops developed through other conventional breeding methods; however, if transgenic crops are planted on significantly larger acreages than conventional crops, GM crops could pose a greater threat for contamination due to the higher quantity present in the environment. In organic crops, the National Organic Program rules define GM material as an "excluded method"[37] not a "prohibited substance;" accordingly, the unintended presence of GM material in an organic crop would not impact a grower's organic certification. GM contamination of either conventional or organic crops could theoretically result in the loss of sale to some markets if the market requires a GM-Free product; it is important to note, however, that most markets, including the EU, Japan, Australia/New Zealand do allow foods labeled and sold as non-GMO to contain threshold *de minimus* levels of approved GM ingredients (See Economics and Market section below).

In the case of papayas, GM papayas have been shown to impact both conventional and organic growers at some level; scientists and anti-GMO activists, however, offer conflicting reports of the extent of GM transgene movement into non-GM papaya plants. A study by Richard Manshardt[38], a professor at the University of Hawaii's Tropical Plant and Soil Sciences department who helped create the GM papaya, found no evidence of GM material in a non-GM papaya field located 400 meters downwind from a field planted with GM papaya. In trees planted in border rows immediately adjacent to GM papaya trees, cross-pollination ranging from 13-70% between GM and non-GM papaya was found, showing a weak negative correlation with distance from the nearest GM papaya tree. A report developed by Hawaii SEED (formerly GMO Free Hawaii)[39] found that samples of mostly organic and feral papaya seeds on average had GM contamination of non-GM papaya tree seeds to be on the order of 50% on Hawaii Island, <5% on Oahu, and only trace contamination on Kauai (0.0%). In Manshardt's study he found the data indicated that the major source of transgenic contamination in organic fields is seeds of unverified origin, rather than pollen drift from neighboring transgenic fields. There has also been a low level of varietal mixing found in the 'Waimanalo' papaya seed, University of Hawaii's non-GM papaya seed [40]. The Hawaii SEED study found GM contamination of the University of Hawaii's non-GM papaya seed (Waimanolo Solo variety) to be between 0.01% and 0.1%. These contamination rates are well below the 0.9% *de minimus* level acceptable in the E.U. According to Manshardt the contamination levels observed are within acceptable rates for certified seeds of many crops (100% purity cannot be guaranteed with most seeds).

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[36] Lemaux, P. (2009). Genetically Engineered Plants and Foods: (Part II).

[37] National Organic Program Rules. Accessed September 11, 2010 at http://www.ams.usda.gov/AMSv1.0/nop

[38] Manshardt, R.M *et al.* (2005). International Society for Horticultural Science's International Symposium on Papaya 2005. Acta Horticulturae 740. Abstract accessed on September 11, 2010 at http://www.actahort.org/members/showpdf?booknrarnr=740_21.

[39] Bondera M. and M. Query (2006). Hawaiian Papaya: GMO Contaminated. Hawaii SEED. Accessed on September 11, 2010 at http://www.hawaiiseed.org/issues/papaya/papaya-contamination

[40] Grass J., K. Leo (October 13, 2004). Controversy rains on GMO crops. CropChoice News accessed on September 11, 2010 at http://www.cropchoice.com/leadstry062a.html?rceid=2790

According to a 2009 study[41], biotech crops have added important increases in global production of corn, cotton, canola and soybeans since 1996. The study shows that between 1996 and 2007 the average yield impact across the total area planted to insect resistant GM corn and cotton was +6.1% and +13.4%, respectively. The study also reports that while herbicide tolerant (HT) GM varieties have provided the primary benefits of increased cost effectiveness and easier weed control to farmers, a number of varieties have delivered higher yields in some countries (e.g. HT soybeans in Romania, HT corn in Argentina and Philippines). While biotechnology and GM crop advances show great promise, the Union of Concerned Scientists suggest that investments in these technologies may need to be weighed against investments in other proven traditional technologies. In 2009 the Union of Concerned Sciences (UCS) conducted a scientific review to evaluate the overall yield effect of GM for the two primary food and feed crops in the United States, corn and soybeans[42]. The UCS study cautions that despite increases in operational yields (obtained under field conditions when environmental factors result in less than ideal yields) as a result of GM crops there has been no overall increase observed with intrinsic yields (highest yield achievable under ideal conditions). The UCS report does not discount the possibility of genetic engineering eventually contributing to increase intrinsic crop yields. It does, however, suggest that it makes little sense to support genetic engineering *at the expense* of traditional technologies.

California is unique from other regions and houses great diversity of people, natural environments, and agricultural crops and systems. With this increased diversity comes the increased potential for benefits as well as possibly unique risks associated with biotechnology and specifically, GM crops. To date, the majority of crops grown in California, and more specifically, in Monterey County, tend to be specialty crops and not GMOs (the big four GM crops are corn, soy, cotton, and canola). According to the California Council on Science and Technology[43], California shares some of the transgenic crops that are being cultivated across the nation and will benefit from the data collected on such crops here and elsewhere in the U.S. However, California will be one of the only U.S. states testing many transgenic crops of fruits, vegetables, and nuts (California's specialties). For some of these crops, transgenic cultivars are being developed and may require additional consideration to assess their risks and benefits to California's diverse environment.

Growers in Monterey County have not demonstrated an interest in GM crops to date. No commercial GM crops are known to grow in Monterey County and none are currently anticipated to be grown. An herbicide-tolerant lettuce was in development, but it was not brought to market due to a lack of grower interest and an overall reluctance among the local agricultural industry to utilize this technology[44]. However, GM technology may be an important solution to as yet unknown problems that may confront Monterey County agriculture in the future. For example, GM technology is being investigated as a possible answer to Pierce's disease, a fatal bacterial

[41] Brookes, G. and P. Barfoot (May 2009). GM Crops: Global Socio-Economic and Environmental Impacts 1996-2007. PG Economics Ltd., Dorchester, UK.
[42] Gurian-Sherman, Doug (April 2009). Failure to Yield: Evaluating the Performance of Genetically Engineered Crops. Union of Concerned Scientists Publications, Cambridge, MA.
[43] CCST (June 2002). Benefits and Risks of Food Biotechnology.
[44] Stahl, Zachary (March 6, 2008). Citizens' group wants a law to ban genetically engineered crops. Monterey County Weekly.

disease of grapevines[45]. Should the glassy-winged sharpshooter, the vector for this disease, become established here it could devastate the wine grape industry. Currently Monterey County is spending more than $250,000 annually to prevent glassy-winged sharpshooter's establishment in the County. The potential application of GM technology to Pierce's Disease prevention is just one of many examples of potential benefits to Monterey County agriculture.

Economics and Market

The Overall Economic Development Committee of Monterey County action plan calls for the creation of a wider diversity of employment opportunities and support key industries, like agriculture, so they remain competitive, innovative and profitable while diversifying the region's job base[46]. Biotechnological research and innovations may offer the potential to help Monterey County achieve these goals. As stated above, leading biotechnology and food safety researchers report that the existence of an anti-biotech ordinance in Monterey County has dissuaded researchers from conducting biotechnology research in county.

In a 2010 study conducted by the National Research Council[47], it is reported that many adopters of GM crops have experienced lower costs of production, higher crop yields, or both. The study also reported that farmers value the increases in worker safety as well as greater simplicity and flexibility in farm management associated with the adoption of GM crops.

In 2007 the direct global farm income benefit from biotech crops was $10.1 billion through enhanced productivity and reduced inputs[48]. According to Brookes and Barfoot's study, 58% of the farm income benefits were earned by developing country farmers. In examining the cost farmers pay for accessing GM technology, the study found that farmer's net cost for the technology was lower in developing countries than those in developed countries; more specifically, farmers in developing countries total cost was 14% of the total technology gains, while in developed countries farmer cost was 34% of the total technology gains. This difference in cost for accessing technology between developed and developing nations reflects factors such as weaker provisions for, and enforcement of, intellectual property rights in developing countries and the higher average level of farm income gain on a per acre basis derived by developing country farmers relative to developed country farmers.

Serious concerns have arisen due to the consolidation of the seed industry as a result of a number of factors including the Supreme Court decisions allowing agricultural biotechnology and other plant products to be patented. The U.S. Department of Justice announced in August 2009 that it would investigate anticompetitive conduct in the seed industry; the top four firms account for 50

[45] Kirkpatrick, B., J. Labavitch, A. Dandekar, and C. Meredith (2001). Genetic transformation to improve the pierces disease resistance of existing grape varieties. Available at http://www.pircesdisease.org/papers/36.

[46] Overall Economic Development Commission (2002). Monterey County Economic Development Action Plan. Accessed on September 11, 2010 at http://www.mcbusiness.org/page/montereycounty_econdev/index.v3page;jsessionid=4ro2a6vp380ep

[47] National Research Council (2010). The Impact of Genetically Engineered Crops on Farm Sustainability in the United States. National Academy Press, Washington, D.C.

[48] Brookes, G. and P. Barfoot (May 2009). GM Crops: Global Socio-Economic and Environmental Impacts 1996-2007.

percent of the proprietary market and 43% of the commercial market[49]. Monsanto Company has taken the number one position among its several competitors over the past decade.

According to the Farmer to Farmer Campaign December 2009 report "Out of Hand," three major trends have emerged in the Monsanto-dominated seed marketplace that prove challenging to farmers. First, historic price increases in seed has been driven by GM trait royalty fees, with unmatched price increases by the Monsanto Company. Second, because each GM trait carries a separate royalty fee, higher seed prices have also resulted from stacking multiple traits into single varieties (and limiting the availability of single-trait seed). While Monsanto has been able to leverage its market share to drive trait stacking, some of this is also driven by the fact that certain single trait varieties (Bt) are not encouraged due to the potential for the development of faster insect resistance[50]. Lastly, as the seed industry consolidates, seed options narrow and farmers lose access to important varieties they have relied on (such as non-GM or single GM trait varieties). In recent years demand for non-GM soybeans, which is now in limited supply, has increased due to a number of factors, including: high seed and glyphosate costs, glyphosate-resistant weeds, high premiums for conventional soybeans and the ability to save non-patented varieties of seeds. A National Research Council study[51] echoes that the current developmental trajectory of GM-seed technology towards multiple stacked traits is causing some farmers of soybean, corn and cotton to express concern that access to seeds without GM traits or to seeds that have only the specific GM traits that are of interest will become increasingly limited.

Consumer acceptance of genetically modified foods has been more negative in developed countries than developing countries. The generally positive attitude toward genetically modified foods in developing countries likely stems from more urgent needs of food availability and nutritional content[52]. A meta-analysis of 25 genetically modified food valuation studies found that across all studies, consumers on average place anywhere from 23-42% higher value for non-GM food relative to GM food; European Union (EU) consumers placing higher value on non-GM food than North American consumers[53]. Based on their findings, Lusk *et al.* report that valuations are significantly affected by study methodology, and it is far more complicated to determine which valuation estimates are best suited for cost-benefit analysis to inform policy making.

One factor that has historically hampered the coexistence of GM and non-GM crops is "zero tolerance" for GM presence. Achieving 100% purity with any biological system is impossible and would require a complete ban on growing GM crops[54]. In a climate of zero tolerance, a producer whose crop has been contaminated with GM material could lose income if they have a buyer-farmer contract guaranteeing 100% GMO free.

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[49] Hubbard, K. (December 2009). Out of Hand: Farmers Face the Consequences of a Consolidated Seed Industry. National Family Farm Coalition. Available at www.farmertofarmercampaign.org.

[50] Lemaux, P. 2009. Genetically Engineered Plants and Foods (Part II).

[51] NRC (2010). The Impact of Genetically Engineered Crops on Farm Sustainability in the United States.

[52] Curtis, K.R., J.J. McCluskey, T.I. Wahl (2004). Consumer Acceptance of Genetically Modified Food Products in the Developing World. *AgBioForum* 7(1&2):70-75.

[53] Lusk, J.L. *et al.* (2005). A Meta-Analysis of Genetically Modified Food Valuation Studies. *Journal of Agricultural and Resource Economics* 30(1):28-44.

[54] Lemaux , P. (2009). Genetically Engineered Plants and Foods (Part II).

According to an examination of export market concerns surrounding GM crops[55], the European Union prohibits the import of shipments containing GM crops that have not been approved in those countries and have a zero tolerance for food imports containing unapproved GM ingredients. The European Union, Japan and Australia/New Zealand do allow foods labeled and sold as non-GMO to contain threshold values of approved GM ingredients as long as they contain less than 0.9%, 5% and 1%, respectively. Biotech is gaining acceptance in other regions of the world. In a landmark decision in November 2009, China approved the use of biotech rice and corn developed entirely with public sector resources from the government[56]. While the concern over possible lost market for GM crops persists, to date there has been only limited loss of U.S. export revenue from some markets that were closed to GM products.

Human Health[57]

Genetically modified foods currently available on the international market have passed risk assessments and no adverse human health effects have been observed resulting from the consumption of such foods[58] [59] [60] [61]. Most human health concerns raised by interest groups and activists relate to the *consumption* of genetically modified foods. The health concerns about the consumption of GM food, however, are not directly addressed by the current referral to enact a moratorium on *growth and cultivation* of genetically modified organisms, specifically GM crops. Biotechnological approaches have resulted in many advances to benefit human health.

With the ability to translocate genetic material from unrelated species it is possible that allergens may be introduced to otherwise non-allergenic foods. No allergic effects have been found relative to GM foods currently on the market[62]. In some cases bioengineering has actually been used to reduce the allergenicity of certain foods. Though not on the market yet, successful examples of bioengineering approaches that reduce allergenicity in foods include wheat, rice, soy beans and peanuts.

While there is no specific federal requirement that foods be labeled to specify that they contain genetically engineered materials, the FDA's labeling policy for foods requires that GM foods be labeled in the same way as for non-GM foods. Consumers must be given information about nutritional, health safety, or food quality changes in the product. For example, foods engineered with new, potentially allergy-causing proteins must be labeled appropriately to state the allergen and name its source. It is possible, however, that if GM material that contained an allergenic substance were to contaminate a non-GM crop, the allergen could be introduced into the food

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[55] Lemaux , P. (2009). Genetically Engineered Plants and Foods (Part II).

[56] James, C. (2009). Global Status of Commercialized Biotech/GM Crops: 2009.

[57] Unless otherwise noted, this section contains information summarized by Lemaux, P. (2008). Genetically Engineered Plants and Foods (Part I).

[58] WHO (2010). 20 questions on genetically modified foods. Accessed on September 3, 2010 at http://www.who.int/foodsafety/publications/biotech/20questions/en/

[59] G.J. Persley, The Doyle Foundation. Executive Summary for New Genetics, Food and Agriculture: Scientific Discoveries-Societal Dilemmas. International Council for Science, June 2003. Accessed on April 26, 2010 at http://www.icsu.org/2_resourcecentre/INIT_GMOrep_1.php4 .

[60] Schmidt, C.W. (2005). Genetically modified foods: breeding uncertainty. Environ Health Prespect., 2005 Aug; 113(8): A526-33.

[61] NRC (2004). Safety of Genetically Engineered Foods.

[62] WHO (2010). 20 Questions on Genetically Modified Foods.

system and remain unlabeled (since the non-GM crop is not allergenic in its uncontaminated state), or vice versa.

The International Council for Science's (ICSU) analysis of 50 reviews published from 2000 to 2003 draws several conclusions and summarizes points of convergence and divergence in the literature. The ICSU concluded that GM foods are safe to eat; millions of meals have been prepared with GM ingredients since their introduction in 1995 and no demonstrated adverse effects have been shown. The ICSU notes that while this may be broadly true, even proponents (or those generally supportive of GMOs) acknowledge there may be future issues as new varieties are brought to market.

As of the publication date of the National Research Council's 2004 assessment of the safety of genetically engineered foods, no adverse health effects attributed to genetic engineering had been documented in the human population. The NRC goes on to recommend a series of actions believed necessary to insure the health and safety of foods containing genetically modified material, including but not limited to genetically engineered materials. Specifically, the report recommends that:

1. Compositional changes that result from all genetic modification (not just genetic engineering) in food undergo appropriate safety assessment,
2. The appropriate federal agencies determine if evaluation of GM foods for potential adverse health effects is warranted by elevated concern,
3. For foods warranting further evaluation, a safety assessment should be conducted prior to commercialization and continued evaluation post-market where safety concerns are present,
4. Standardized sampling methodologies, validation procedures, and performance-based techniques of GM food be developed and employed,
5. In cases that warrant it, the tracking of potential health consequences from commercially available GM foods should be improved,
6. Research effort should be made to support analytical methods and tools to detect population health changes as well as to determine the relevance to human health of dietary constituents that arise from or are altered by genetic modification.

Different crops have been used to produce vaccines for both humans and animals and research is underway to develop more pharmaceutical products in plants. In 2002 the National Research Council[63] stated that the introduction of transgenes from biotechnology applications, such as pharmaceutical products, biologics, fuels and other substances not intended for human food use, poses the potential for environmentally associated risks of a wholly different order than those associated with existing transgenic crops. If such a transgene ends up in food, there could be serious human health risks. While the FDA and USDA have many rules in place to prevent contamination of food crops from these types of biotechnologies, there persists the possibility that such products could enter the food supply. Given the near certainty that gene flow will happen when compatible plants (agricultural or natural) are present near crops that may be genetically engineered for a non-food use, and that GM crops are able to persist in the environment, the risk of incidental contamination of food crops by pharma-crops is a disconcerting possibility that could have serious health risks.

[63] National Research Council (2002). Environmental Effects of Transgenic Plants.

As summarized in a 2005 report for Congress[64], material from GM-altered corn plants that had been test-planted in a prior growing season in Nebraska for pharmaceutical use (by ProdiGene, Inc.) was inadvertently mixed in 2002 with some 500,000 bushels of soybeans in 2002. The soybeans had to be quarantined by USDA to keep them out of the food supply. In a December 6, 2002, press release, USDA announced that ProdiGene had agreed to pay a civil penalty of $250,000, to reimburse USDA for destroying the beans, post a $1 million bond, and meet higher field testing compliance standards. USDA officials observed that the soybeans never reached the food or feed supply, evidence that current regulatory oversight is effective. Following this incident USDA regulation governing testing of pharmaceutical crops was tightened. These tightened rules require a permit to grow pharmaceutical crops, inspections of crops seven (7) times/year with twice after harvest, increase field isolation distances, and dedicated farm equipment. Critics countered that the ProdiGene case illustrates the dangers of growing plant-based drugs, and predicted a consumer backlash if government regulation is not strengthened. Proponents argue that careful management and oversight of test sites can address such concerns.

Natural Environment[65]

A 2002 California Council of Science and Technology report finds that genetically engineered crops may hold both promise and peril for the environment depending upon a variety of factors including the type of GM crops grown, the nature of the GM traits involved, and the geographic location of crops in relation to wild relatives[66]. Gene flow will occur when compatible (flowering) plants are present and share reproductive cells, thus GM traits can move and persist in unintended plants. At modest acreages those concerns are not significantly greater for transgenic crops than those posed by most crops developed through conventional breeding methods. Environmental contamination has not been a reported problem for the majority of GM crops to date[67]. Since generalizations about whether gene flow presents significant environmental risks cannot be made either for traditional (non-GM) bred or GM crops, a case-by-case evaluation is necessary.

All three federal agencies that oversee GM crops have legal rights to demand immediate market removal of any product if valid scientific data show safety concerns for consumers or the environment. While the federal agency oversight is in place, it has primarily been the US court system that has made inquiries regarding the environmental impact of two GM crops, GM bentrass and Roundup Ready alfalfa. GM bentgrass pollen was found to have spread 13 miles from its cultivation site and Roundup Ready alfalfa which the court system ruled that USDA-APHIS had erred in approving deregulation without an environmental impact statement.

Chemical (e.g. herbicide, pesticide, fungicide) usage associated with growing food and fiber crops is a concern, and the impact of biotech crops on chemical usage is an important

[64] Becker, G.S. and D. Vogt (March 8, 2005). Regulation of Plant-Based Pharmaceuticals. Congressional Research Service Report for Congress: Order Code RS21418.

[65] Unless otherwise noted, this section contains information summarized by Lemaux, Peggy (2009). Genetically Engineered Plants and Foods (Part II).

[66] California Council of Science and Technology (June 2002). Benefits and Risks of Food Biotechnology. Sacramento, CA.

[67] National Research Council (2010). The Impact of Genetically Engineered Crops on Farm Sustainability in the United States.

consideration. To provide a more robust measurement of the environmental impact of the chemical usage associated with adoption of biotech crops, analyses should include both an assessment of chemical active ingredient (AI) use, as well as the assessment of the specific pesticides used via an indicator known as the Environmental Impact Quotient (EIQ)[68,69]. The EIQ (or EI) integrates the various environmental impacts of individual pesticides into a single 'field value per acre.' This provides a more balanced assessment of the impact of biotech crops on the environment as it draws on all of the key toxicity and environmental exposure data related to individual products (applicable as well to impacts on farm workers, consumers and ecology) and hence provides not only a consistent but a fairly comprehensive measure.

In a review of existing literature, Dr. Peggy Lemaux (2009) reviewed numerous studies conducted on chemical usage resulting from herbicide/pesticide resistant GM crops. She summarized that some studies showed pesticide use, expressed as chemical active ingredient (AI) per unit area, decreased with introduction of GM HT and Bt crops; some studies showed increases. More recent studies were focused on the environmental impact (EI), as opposed to AI, and show reductions in the EI, including on farm workers, consumers, and the natural environment. The National Research Council's 2010 study[70] concluded that application of Bt technology in corn and cotton has successfully decreased insecticide applications. The NRC also concluded that adoption of herbicide resistant crops could help improve soil and water quality due to reduced soil tillage; unfortunately, there is no infrastructure in place to track and analyze this likely benefit.

In their 2009 report evaluating the global impact of genetically engineered crops, Brooks and Barfoot found that since 1996, in the U.S. and globally, the introduction of GM crops with insect and herbicide resistance traits has resulted in cumulative reductions in chemical usage measuring both the AI and EIQ for six GM crop being grown commercially (see Table 1).

TABLE 1: U.S. and Global Cumulative Impact of GM Crops on Pesticide/Herbicide Use Since 1996 (Brooks and Barfoot 2009)

GM CROP	CUMMULATIVE AI (US / GLOBAL)	CUMMULATIVE EIQ (US / GLOBAL)
HT Soybeans	↓ 5.76% / 4.6%	↓ 28.6% / 20.9%
HT Corn	↓ 6.2% / 6.0%	↓ 6.9% / 6.8%
HT Cotton	↓ 15.9% / 15.1%	↓ 16.0% / 16.0%
HT Canola	↓ 33.0 % / 13.0%	↓ 44.0% / 25.8%
Bt Corn	↓ 21.6% / 5.9%	↓ 20.7% / 6.0%
Bt Cotton	↓ 8.3% / 23.0%	↓ 33.0% / 27.8%

[68] Lemaux, P. (2009). Genetically Engineered Plants and Foods: (Part II).

[69] Brooks, G. and P. Barfoot (May 2009). GM Crops: Global Socio-Economic and Environmental Impacts 1996-2007.

[70] National Research Council (2010). The Impacts of Genetically Engineered Crops on Farm Sustainability in the United States.

Some concerns have been expressed about weeds developing tolerance to herbicides and the possible development of super-weeds which could reduce or negate observed reductions in chemical usage attributed to HT GM crop adoption. As summarized in Lemaux (2009)[71], problems with herbicide-resistant weeds are real, but not new; weed resistance has also occurred with traditionally bred crops. Historically herbicide resistance arose out of herbicide overuse or movement of conventional herbicide-tolerance traits to weedy species, resulting in plants not controllable with previously applied herbicides. The same situation can occur with HT GM varieties. Although "environmental disasters" such as super-weed development is not likely to occur, it does reduce the effectiveness of certain weed control strategies and decreases weed management options. Lemaux (2009) also summarizes data indicating that certain weeds have developed tolerance to the herbicides glyphosate (Roundup®) and glufosinate (Liberty®), currently the only two herbicides used in GM crops. A third resistance mitigated by a naturally occurring gene provides tolerance to the herbicide variety Clearfield®.

Overuse of single herbicides can lead to this situation and reduces the efficacy of HT crops. The NRC's 2010 report specifically recommends that in order to limit the evolution of glyphosate-resistant weeds, farmers of herbicide-resistant GM crops should incorporate more diverse management practices than glyphosate-only applications. HT weeds can also arise because of outcrossing with HT GM crops. Wild species compatible with canola do exist in North America and hybrids have been observed in Quebec, Canada between HT canola and *Brassica rapa*. Despite lower fertility of these hybrids, the HT transgene persisted in the *B. rapa* population without herbicide applications from 2003 to 2008. Overuse of herbicides can also result in weed shifts, where weeds naturally resistant to an herbicide encroach upon areas where the herbicide is in use. Brooks & Barfoot report that the management practice changes and associated environmental impact of theses changes required to address issues such as weed resistance associated with GM crops are likely to be relatively minor. While Brooks & Barfoot conclude that the benefits observed of reduced chemical usage would only be marginally reduced in order to deal with issues of weed resistance, out crossing and weed shifts, Lemaux cautions that the development of either herbicide-resistant weeds or weed shifts with HT crops might negate the positive environmental benefits of HT crops.

With a few minor exceptions[72], the evolution of Bt-resistant insects has been abated due largely to a successful refuge strategy mandated by the EPA[73]. The strategy mandates that a certain percentage of every Bt field must be planted with non-Bt seed to ensure that a population of insects susceptible to Bt toxins will survive and mate with any insects that develop resistance, thus reducing resistance development in the insect population.

A similar concern is the movement of GM crops to non-crop areas, including roadsides and environmentally sensitive areas. As discussed above, though GM crops have not shown a greater likelihood of movement into non-crop areas than non-GM crops; the concern is heightened for GM crops that have an herbicide resistance trait. In Yolo County, California, for example, genetically modified Roundup® ready canola, along with conventional, non GM canola, has

[71] Lemaux, P. (2009). Genetically Engineered Plants and Foods (Part II).
[72] Lemaux, P. (2009). Genetically Engineered Plants and Foods (Part II).
[73] NRC (2010). The Impacts of Genetically Engineered Crops on Farm Sustainability in the United States.

been found growing on roadsides near farms. The primary management concern associated with GM canola is the treatment methodology; mechanical control or an herbicide other than Roundup must be used to effectively treat the plant (and there are at least 2 other herbicides successfully used to do so).

Unintended consequences of GM crops, particularly those engineered for pest resistance, on non-target insect or animal species is a topic of continued research and scientific discussion. In the now (in)famous short paper in the May 20, 1999 issue of *Nature* Scientific Correspondence section[74], Dr. John Losey and colleagues reported that monarch butterfly larvae exposed to Bt corn pollen in a laboratory ate less milkweed than those exposed to conventional pollen and suffered 44% mortality within four days (compared to no mortality for larvae exposed to conventional pollen). This short paper sparked a worldwide controversy placing the monarch butterfly as the poster-child for the dangers of agricultural biotechnology. In response, the leadership of the USDA, public and private scientists and environmental groups worked together to develop a consensus set of experiments published in the *Proceedings of the National Academy of Sciences* (2001) that eventually showed that the risks of GM corn to monarchs are fairly small[75].

As the Pew study (2003) points out, this controversy raised important questions about the EPA's process for reviewing GM crops for environmental impacts. It also illustrates a highly successful collaboration between agencies, industry and private researchers to investigate a concern and provide a scientifically founded consensus to inform the regulatory process. Unfortunately, it also raises questions about the role of scientific journals and the mainstream press in covering scientific news for controversial issues: The general public remembers the media frenzy over the *Nature* study but is hardly aware that the scientific community subsequently resolved the question and alleviated concerns for monarch impacts.

As discussed in detail above in Human Health, while some studies looking at chemical usage associated with adoption of GM crops have conflicting findings, more recent studies that focus on EI show reductions in pesticide impact both the U.S. and globally. Studies that focus on EI provide a more accurate way to determine chemical usage and its impact on the natural and human environment. While additional efforts may be necessary to further reduce EI of agricultural production, these reductions in agricultural chemical impact to the environment are paramount to safeguarding our ecological communities. In the case of the monarch butterfly, for example, field corn is treated occasionally and sweet corn treated commonly (10-15 times) with chemical insecticides[76]. Mortality rates of monarchs in corn fields that were chemically treated were significantly higher than those observed with Bt corn, presenting a much greater risk to the monarchs.

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[74] Losey, J.E., L.S. Raynor, and L.E. Carter (1999). Transgenic pollen harms monarch larvae. *Nature* 399:214.

[75] Pew Initiative on Food and Biotechnology (2003). Three Years Later: Genetically Engineered Corn and the Monarch Butterfly. Accessed on September 11, 2010 at http://www.pewtrusts.org/our_work_report_detail.aspx?id=33380.

[76] Hellmich, R.L. (March 8, 2008). Monarch Butterflies and Bt Corn. Accessed on September 11, 2010 at http://agribiotech.info/details/Hellmich-Monarch%20Mar%208%20-%2003.pdf

As also discussed in more detail above in Human Health, scientists believe that the introduction of transgenes from biotechnology applications, such as pharmaceutical products, biologics, fuels and other substances not intended for human food use, poses the potential for environmentally associated risks of a wholly different order than those associated with existing transgenic crops. If such a transgene moves into a wild relative, there could be widespread dissemination of the pharmaceutical or other nonfood substances that could have impacts on wildlife as well as microbial populations.

Also as discussed in detail above in Natural Environment, there is some disagreement amongst scientists whether weed tolerance in relation to GM crops is a relatively minor issue that will result in only small decreases to the observed reductions in chemical usage or if tolerance could eventually negate the observed benefits and reductions in chemical usage. With minor exceptions, current strategies have successfully prevented the evolution of Bt-resistant insects.

SUMMARY

Just over half of the counties in California have taken or considered taking action either in favor of or against GMOs over the past decade. Ten counties considered but did not pursue ordinances; of the counties that have taken action, four counties voted on and passed anti-GMO ordinances, four voted on and rejected anti-GMO ordinances, and twelve adopted pro-biotechnology ordinances.

Interestingly, consumer and political acceptance of genetically modified foods has been more negative in developed countries than developing countries, likely stemming from more urgent needs of food availability and nutritional content in the developing world. China, for example, recently approved the use of biotech rice and corn developed entirely with public sector governmental resources. The European Union, on the other hand, prohibits the import of shipments containing GM crops that have not been approved in those countries. The EU, Japan, and Australia/New Zealand do, however, allow foods labeled and sold as non-GMO to contain threshold values of approved GM ingredients as long as they contain less than 0.9%, 5%, and 1% respectively. This allowance is largely due to the reality that crops are grown in open air conditions and for the top GM crops, some level of mingling between GM and non-GM material is unavoidable.

The top GM food crops are corn, soybeans, and canola; these products are now commonly found in most crackers, chips, snacks, soy products, etc. purchased and sold throughout the country. There is no specific federal requirement that foods be labeled to specify that they contain genetically engineered materials; rather, the FDA's labeling policy for foods requires that GM foods be labeled in the same way as for non-GM foods (with nutritional information, for example).

The summary of issues within this report was limited to peer-reviewed publications that provide analysis, review, or summary of a larger body of primary scientific literature. Some key points of consideration and themes in the realms of agricultural, environmental and human health are as follows:

I. Seed Industry Consolidation: The trend of seed industry consolidation and trait stacking raises considerable concern about the continued availability of both single trait GMO varieties and non-GMO seeds, particularly for corn, soybean, and cotton. Such concern is unresolved in the global market place and unlikely to be resolved with a local political process.

II. Crop Contamination & Farmer Liabilities: Serious concern about crop contamination in both organic and non-GMO fields have been raised. Importantly, in California, AB 541 became law in 2008 and protects growers who may have crops contaminated with *de minimus* amounts of GM material from patent-holder lawsuits. Also of importance, in the United States, pursuant to the National Organic Program rules, the unintended presence of *de minimus* GM material in an organic field does not threaten the organic certification of a crop.

III. Potential Environmental Contamination: This report found little credible, scientific evidence that GMOs pose significantly more threats of gene flow and environmental drift than do conventionally bred crops. Concerns have been expressed about "superweeds," weeds that develop tolerance to herbicides. This report found that problems with herbicide-resistance weeds are real, but not new, since herbicide resistance arises from single herbicide overuse and can occur with both GM and non GM varieties. There is, however, some disagreement amongst scientists about whether or not weed tolerance in relation to GM crops could eventually negate the observed benefits of GM crop's decreased herbicide usage.

IV. Human Health: Importantly, health concerns raised about the *consumption* of GM food are not directly addressed by the current referral to consider enacting a moratorium on the *growth and cultivation* of genetically modified organisms, specifically GM crops. Regardless, scientific publications reviewed for the preparation of this report indicate that genetically modified foods currently available on the international market have passed risk assessments and no adverse human health effects have been observed resulting from the consumption of such foods. No allergic effects have been found relative to GM foods currently on the market.

V. Nonfood Crops: Though not the focus of this report, the introduction of transgenes from biotechnology applications such as pharmaceutical products, biologics, fuels and other substances *not* intended for human food use, poses the potential for human and environmental health on a wholly different order than transgenic crops.

VI. Regulatory Oversight & Complexity: The United States Department of Agriculture APHIS opened its regulatory framework for public review in 2008 and 2009; comments received are currently under review. The National Research Council and, separately, the Government Accountability Office have both identified key areas for improvement in the federal agency coordinated regulatory framework. In addition, on the state level, findings of this report indicate that states generally seek a collaborative relationship with federal agencies in both initial approval decisions and compliance oversight. However, due to limited technical, financial, and scientific

capacities, states do not appear to support the development of duplicative scientific review capacities and regulatory processes.

Monterey County is an agricultural community with health and environmentally conscious businesses and residents. GM crops have not gained demonstrable interest by the agricultural industry. There are, however, research operations for both food and non-food crops that utilize breeding techniques including marker assisted selection. In fact, highly technical breeding programs are a key component of all the top crops in the county, including: strawberries, lettuce and nursery crops. In addition, agricultural producers maintain an interest in the development and utilization of biotechnology for serious pests or disease problems that may occur in the future.

The issues surrounding GMOs are highly complex, on both regulatory and scientific levels. Concerns about the potential environmental and human health impacts have been and continue to be studied extensively. Due to the complexity of the regulatory and scientific issues surrounding GMOs, our analysis relied on peer reviewed scientific publications that provide review and summary of the larger body of primary literature. Regulatory and scientific complexities aside, however, GMOs also bring about a level of emotional, ideological, and political complexity that is outside of the scope of this research, but must also be carefully considered by decision-makers.

APPENDICES

APPENDIX 1: Monterey County Zoning Ordinance 21.64.140
APPENDIX 2: April 14, 2008 Memo from Supervisor Dave Potter Regarding Board Referral to Enact a Moratorium on Genetically Modified Organisms in Monterey County
APPENDIX 3: Mendocino County Code, Title 10A, Agriculture, Chapter 15 Prohibition of the Propagation, Cultivation, Raising and Growing of Genetically Modified Organisms in Mendocino County
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APPENDIX 11: Stanislaus County Resolution in Support of the Use of Biotechnology in the Agricultural Industry (2005)
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APPENDIX 1: Monterey County Zoning Ordinance 21.64.140

21.64.140 - Regulations for the location and siting of genetic engineering experiments.

A. Purpose: The purpose of this Section is to establish a uniform County regulatory policy, standards, and permitting process pertaining to the location and siting of experiments involving the release of genetically engineered microorganisms into the environment with the end in view that public health and safety and the environment are afforded the maximum degree of protection. It is not the intent of this Section to enter the regulatory sphere occupied by the federal and State government; rather, it is the ntent of this Section to use land use plans and zoning ordinances as primary guides in the determination of proper location for the conduct of genetic engineering experiments.

B. Applicability: This Section is applicable to any and all experiments involving the release of genetically engineered microorganisms into the open environment conducted by any person or agency. It is not applicable where the experiment proposed has already been conducted without any adverse impacts on public health and safety and the environment, on a crop within the same crop grouping, as defined in 40 C.F.R. 180.34, within the United States.

C. Findings:

1. Experiments involving the release of genetically engineered microorganisms into the open environment may pose risks to public health, safety, and the environment not adequately addressed under current federal and State regulations.
2. While the control of the release of genetically engineered microorganisms into the environment may generally be considered the responsibility of federal and State governments, it is local government that may initially be called upon to respond to any adverse effects to public health, safety, and the environment, resulting from the release of such microorganisms into the open environment.
3. In order for local government to have the capacity to provide appropriate response in such instances, it is, at a minimum, necessary for local government to be able to determine sites within its jurisdiction appropriate for the conduct of such experiments within the parameters of its land use prerogatives.
4. In order to protect the public health, safety, and the environment, it is in the public interest for local government to establish rules and regulations addressing certain land use aspects of such experiments, including suitability of test sites and their compatibility with surrounding land uses.

D. Definitions:

1. "Agency" means any local agency as defined in Section 53090 of the government Code. It does not include the federal government or any agencies thereof.
2. "DNA" means deoxyribonucleic acid.
3. "Genetically engineered microorganisms" means microorganisms including bacteria, fungi, protozoa and viruses, created or modified by recombinant (rDNA) technology which are nonpathogenetic to humans and animals.
4. "Genetic engineering" means a process or technology employed whereby the hereditary apparatus of a living cell is altered, modified, or changed so that the cell can produce more or different chemicals or perform completely new functions.
5. "In vitro" means, literally, in glass. This pertains to biological reactions taking place in an artificial apparatus; sometimes used to include growth of cells from multicellular organisms under cell culture conditions.
6. "Open environment" means any unenclosed area or area in the open or place outside a building or shelter.
7. "Person" means any individual, firm, partnership, trust, corporation, company, estate, public or private institution, association, organization, or group, and any representative, agent, or agency of any of the foregoing.
8. "Recombinant DNA (rDNA)" means the hybrid DNA produced by joining or deleting pieces of DNA from the same or different organisms or synthetic DNA from the same or different organisms or synthetic DNA together in vitro.
9. "Release" means to intentionally or deliberately discharge, emit, or liberate any genetically engineered microorganism into the open environment.

E. Regulations:

1. Genetic engineering experiments are an allowed use on properties designated by the Monterey County General Plan, area plans or coastal land use plans as Farmlands, Permanent Grazing, Rural Grazing, Agricultural Conservation or Agricultural Preservation, except as provided in subsection E.2. below and provided such experiments have been approved by the Agricultural Commissioner.
2. No person or agency shall conduct experiments involving the release of genetically engineered microorganisms into the open environment within one hundred (100) feet of an occupied structure without first obtaining a Use Permit pursuant to Chapter 21.74 of this Title. Chapter 21.74 shall govern all matters relating to Use Permits for such experiments except as provided for in this Section. A Permit

Committee comprised of the Director of Environmental Health, Agricultural Commissioner and Director of Planning shall have the power to hear and decide applications for, and issue such Use Permits,

3. No application for a Use Permit may be considered unless the applicant demonstrates that he/she has been granted the necessary permit to conduct such experiments by the appropriate federal and State agencies at the time of the filing of the application.
4. All Use Permits for experiments involving the release of genetically engineered microorganisms shall require environmental review pursuant to the California Environmental Quality Act and the guidelines adopted by the County of Monterey. Such Use Permits may not be categorically exempt.
5. All Use Permit applications shall be accompanied by all necessary forms, plans and supporting information deemed necessary by the Director of Planning, the Director of Environmental Health and the Agricultural Commissioner to consider the Use Permit application complete. Such information shall include at the minimum:
    a. A site plan showing in sufficient detail and scale:
        i. the size of the property proposed for the use;
        ii. the current use of the property;
    b. Copies of all approved State and federal permits for the use;
    c. Copies of all information submitted to State and federal agencies, except materials and information considered to be "trade secrets";
    d. Information relative to the type of microorganism to be used;
    e. Plans and measures for the control of public access and trespass on the subject site;
    f. Measures for the protection of surface and groundwater;
    g. Measures for vector control;
    h. Measures for control of airborne materials from the site;
    i. Measures proposed for meeting potential liability.
6. Upon the application being deemed complete, it shall be submitted to the Monterey County Agricultural Advisory Committee for a report and recommendation prior to consideration by the Permit Committee.
7. The Permit Committee may impose such conditions as it deems necessary to protect the public health, safety and the environment.
8. The decision of the Permit Committee may be appealed to the Board of Supervisors pursuant to Chapter 21.80 of this title.

F. Financial Assurances and Indemnification:
1. Each permit issued pursuant to this Section shall have as a condition of the permit, a requirement that the applicant provide financial assurances that are necessary to respond adequately to damage claims arising from activities permitted under this Chapter. The financial assurances shall be in the form of a trust fund, surety bond, letter of credit, insurance, or other equivalent financial arrangement in a form and in amounts acceptable to the County.
2. Each permit issued pursuant to this Section shall have, as a condition of the permit, a requirement that the applicant indemnify and hold harmless the County and its officers, agents, and employees from actions or claims of any description brought on account of any injury or damages sustained, including death, by any person or property resulting from the issuance of the permit and the conduct of the activities or experiments authorized under said permit.

C. Severability: If any section, subsection, sentence, clause, or phrase of this Section is for any reason held to be invalid, such decision shall not affect the validity of the remaining portions of this Section. The Board of Supervisors hereby declares that it would have passed this Section and each section, subsection, sentence, clause, and phrase thereof, irrespective of the fact that any one or more section, subsections, sentences, clauses, or phrases may be declared invalid.

(Ord. 3849 § 1, 1995)

(Ord. No. 5135, § 135, 7-7-2009)

APPENDIX 2: April 14, 2008 Memo from Supervisor Dave Potter Regarding Board Referral to Enact a Moratorium on Genetically Modified Organisms in Monterey County

MONTEREY COUNTY

Board of Supervisors

Supervisor Dave Potter
Monterey County, Fifth District Supervisor

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April 14, 2009

Memorandum

To: Lew Bauman, CAO
From: Supervisor Dave Potter

RE: Board referral re: enacting a moratorium on Genetically Modified Organisms in Monterey County

The request is to have the Agricultural Commissioner and the Director of Environmental Health provide a response to the Board of Supervisors that outlines what the process would be for the County to consider adopting a moratorium on genetically modified organisms (GMO's) similar to what was passed in the County of Santa Cruz in 2006.

There are a number of concerns that are raised with the question of potentially banning GMO's in Monterey County, which would need to be thoroughly addressed and researched in a public process prior to this coming to the Board of Supervisors. As some of these topics may address public health, the Environmental Health Director will need to work with the Agricultural Commissioner on this referral. Some of the concerns that would need to be answered are:

- What is the potential impact to the health of the residents in Monterey County due to GMO's being produced in Monterey County and in the marketplace?
- How would we balance the interests of agriculture, research, agricultural workers and the citizens of Monterey County?
- What tools and resources would the Ag Commissioner and / or Environmental Health need in order to implement an ordinance if adopted?
- Is it appropriate for the County to enact and enforce such an ordinance?
- Is this issue better addressed at the federal or state level?
- What would be the time involved in staff time to research issue? What would the cost be for the time necessary to conduct this research?
- What would be involved to do a thorough a public process? What would the cost be for the outreach and public review process?

I appreciate staff's assistance with this referral as it is one of great importance to many people in Monterey County.

Cc: Eric Lauritzen, Allen Stroh, Charles McKee and Gail Borkowski

APPENDIX 3: Mendocino County Code, Title 10A, Agriculture, Chapter 15 Prohibition of the Propagation, Cultivation, Raising and Growing of Genetically Modified Organisms in Mendocino County

CHAPTER 10A.15 PROHIBITION ON THE PROPAGATION, CULTIVATION, RAISING AND GROWING OF GENETICALLY MODIFIED ORGANISMS IN MENDOCINO COUNTY

Sec. 10A.15.010 Finding.

The people of Mendocino County wish to protect the County's agriculture, environment, economy, and private property from genetic pollution by genetically modified organisms. (Measure H-2004, passed March 2, 2004.)

Sec. 10A.15.020 Prohibition.

It shall be unlawful for any person, firm, or corporation to propagate, cultivate, raise, or grow genetically modified organisms in Mendocino County. (Measure H-2004, passed March 2, 2004.)

Sec. 10A.15.030 Definitions.

(A) "Agricultural Commissioner" means the Agricultural Commissioner of Mendocino County.
(B) "DNA" or "deoxyribonucleic acid" means a complex protein that is present in every cell of an organism and is the "blueprint" for the organism's development.
(C) "Genetically modified organisms " means specific organisms whose native intrinsic DNA has been intentionally altered or amended with non-species specific DNA. For purposes of this Chapter, genetic modification does not include organisms created by traditional breeding or hybridization, or to microorganisms created by moving genes or gene segments between unrelated bacteria.
(D) " Organisms " means any living thing.
(Measure H-2004, passed March 2, 2004.)

Sec. 10A.15.040 Penalties.

(A) The Agricultural Commissioner shall notify any person, firm, or corporation that may be in violation of Section 10A.15.020 of this Chapter, that any organisms in violation of this Chapter are subject to confiscation and destruction.
(B) Any person, firm, or corporation that receives notification under subsection (A) shall have five (5) days to respond to such notification with evidence that such organisms are not in violation of this Chapter.
(C) Upon receipt of any evidence under subsection (B), the Agricultural Commissioner shall consider such evidence and any other evidence that is presented or which is relevant to a determination of such violation. The Agricultural Commissioner shall make such determination as soon as possible, but at least before any genetic pollution may occur.
(D) Upon making a determination that a violation of this Chapter exists, the Agricultural Commissioner shall cause to be confiscated and destroyed any such organisms that are in violation of this Chapter before any genetic pollution may occur.
(E) If the Agricultural Commissioner determines there has been a violation of this Chapter, in addition to confiscation and destruction of any organisms that are found to be in violation, the Agricultural Commissioner shall impose a monetary penalty on the person, firm, or corporation responsible for the violation, taking into account the amount of damage, any potential damage, and the willfulness of the person, firm, or corporation.
(Measure H-2004, passed March 2, 2004.)

APPENDIX 4: Co-Existence Methods by Commodity, Their Current Applications in San Luis Obispo County Agriculture, and Implementation of Guidelines (Final Draft 2006)

CO-EXISTENCE METHODS BY COMMODITY, THEIR CURRENT APPLICATIONS IN SAN LUIS OBISPO COUNTY AGRICULTURE, AND IMPLEMENTATION OF GUIDELINES – Final draft 2006

PRE-PRODUCTION PRACTICES			
COEXISTENCE METHOD	COMMODITY	CURRENT APPLICATIONS	IMPLEMENTATION Comments in this column are input from commodity representatives for consideration by industry
COMMUNICATION about decisions, including crop choice, rotations (V, Ma, Minn)	General	Growers decide the best way to communicate information and the resources for technical support (University, CDFA, County Ag, etc.) Technical service providers not standard for all crops.	
	Winegrapes	Good neighbor relationships, Grower associations, Grape acreage reports (industry, county, state)	
	Corn	Limited production is typically part of diversified specialty crops system. No institutional structure or formal groups of specialty crop growers exist locally.	
IDENTIFICATION Ascertain plant or seed purity, seed lines, variety selection, tests for adventitious presence (V, B, Ma, Minn)	General	Due diligence at time of purchase	
	Winegrapes	ENTAV certification and licensing (intellectual property), Certified Nursery Stock, Foundation Plant Material Service disease status, nurseries	
	Corn	Association of Official Seed Certifying Agencies (AOSCA) purity standards for certified seed average 98% across species (AOSCA, 2003). California Crop Improvement Association (CCIA) http://ccia.ucdavis.edu. Branded and patented varieties (for GE have protections in place for both the seed producer and grower) vs non GE or heirloom (patent ran out or non-patented varieties and there are fewer if any protections). Germplasm repositories USDA? supported.	

RECORD KEEPING Who, what, when, where, how, and why (B&B, Ma, Minn)	General	Due diligence for production, e.g., organic regulations, contract requirements, patent requirements, government regulations, identity preservation	
	Winegrapes	ENTAV certification and licensing (intellectual property), Certified Nursery Stock, Foundation Plant Material Service disease status, nurseries	
	Corn	Association of Official Seed Certifying Agencies (AOSCA) purity standards for certified seed average 98% across species (AOSCA, 2003). California Crop Improvement Association (CCIA) http://ccia.ucdavis.edu. Branded and patented varieties (for GE have protections in place for both the seed producer and grower) vs non GE or heirloom (patent ran out or non-patented varieties and there are fewer if any protections). Germplasm repositories USDA? supported. 100,000 seed minimum purchase	Possible actions: Visual labeling (dyes?) of seeds for quick identification of source; storage of GE seeds in pesticide storage

IN-FIELD PRODUCTION PRACTICES (ISOLATION)			
COEXISTENCE METHOD	COMMODITY	CURRENT APPLICATIONS	IMPLEMENTATION
PHYSICAL BARRIERS TO GENE FLOW (Ma, Minn)	General	Windbreak, hedgerow, permanent crops, manufactured barriers	
	Winegrapes	Bird netting impacts to mealybug movement	Grapes are self-pollinating. Flow noted in V. californica
	Corn	Current production is widely dispersed and limited in acreage.	Microclimates and topography limit corn production in SLO.
BUFFER MECHANISMS distances between crops; sequence of planting dates (V, B, Ma, Minn)	General	Rotation, crop-specific buffer systems, offset pollination periods	
	Winegrapes	Spatial buffers for pesticide drift	
	Corn	Seed isolation systems in CA. Varietal selection and roguing – single selection grown per year. Sequence planting dates for different varieties to isolate pollen sources.	Varietal selection and roguing – single selection grown per year. Sequence planting dates for different varieties to isolate pollen sources. Set up buffers with prevailing winds (requires communication system and understanding economic context). California's limited production means Midwest standards of 660 are currently used for buffers – don't have information if this is appropriate for SLO.

PEST RESISTANCE MANAGEMENT PLANS (B&B, Ma, Minn)	**General**	**Integrated Pest Management, rotation, refuges, trap crops (alfalfa and Lygus in strawberries), CDFA/Ag Comm Host Free Periods**
	Winegrapes	Phylloxera resistant rootstock or lack thereof, Herbicide tolerance in mare's tail (*Conyza*)
	Corn	Non Bt selections or pesticide selections for refuge areas. Weed management through rotation into non herbicide tolerant selections or through rotation of chemicals

HARVEST POST-HARVEST PRACTICES			
COEXISTENCE METHOD	COMMODITY	CURRENT APPLICATIONS	IMPLEMENTATION
SANITATION Field sanitation. Calibration, cleaning of rented, custom or own planting, harvesting, transport equipment, storage (V, B, B&B, Ma, Minn	General	Removal of volunteer plants. Organic regulations, contract requirements (e.g. certified seed production, pest sanitation) patent requirements, identity preservation	
	Winegrapes	Industry standard practice for cleanliness and sanitation of harvesting and delivery equipment. Mandated for wines from organic grapes; standard wine-making practice	Maternal tissue in berries; DNA only in seeds
	Corn	Field rotation, eliminate volunteer corn.	
SEGREGATION Tests for adventitious presence, transport, storage (V, B, B&B, Ma, Minn)	General	Organic regulations, contract requirements, patent requirements, identity preservation	
	Winegrapes	Shipping tag control systems, tagging systems for GWSS shipments; segregation of grape and wine lots; contractual requirements food safety	
	Corn	Post-harvest segregation between organic and conventional products; identity preservation systems for certified seed production	
LIABILITY Tort liability (strict liability, strict product liability, trespass, nuisance, negligence, patent infringement liability) **	General	Tort Law currently applies unless GE crops are found to be fundamentally different. Limited case law. Unknown implications for both GE and non-GE producers.	Economic loss doctrine; disappointed commercial expectations.
	Winegrapes	Pesticide use or drift. Materials proscribed by contract. Wine-making specifications tightly controlled by winery.	Liability from growing crops appear to be minimal.
	Corn		

MARKET REQUIREMENTS Sampling and testing protocols, rejection levels or tolerances, paper trail, traceability, labeling	General	Voluntary Labeling Guidelines for Foods Using Bioengineering can be found at www.cfsan.fda.gov/~dms/biolabgu.html.	
	Winegrapes	Winery contract requirements. Processing requirements (yeasts). Country of origin labeling (COOL), Tax and Trade Bureau labeling for origin and varietal identification	Possible negative impacts on markets.
	Corn	Segregation between organic and conventional products; identity preservation systems	

** Information on Patent Infringement Liability is also important for growers to understand. In absence of regulatory programs, liability risk may be increased.

Sources for Methods: V – Vermont. Grubinger and Deziel. 2002. University of Vermont Extension. Transgenic Crop Production in Vermont: Strategies for Co-existence.
B – Bradford k. 2005. Methods to Maintain Genetic Purity of Seed Stocks
B&B – Brookes and Barfoot. 2004. Co-existence in North American Agriculture: Can GM Crops be Grown with Conventional and Organic Crops?
Ma – Maine Department of Agriculture. Date? A Plan for CoExistence
Minn – University of Minnesota. 2004. A Plan for Co-Existence.

APPENDIX 5: Report on Genetically Engineered Food Crops in Santa Cruz County dated May 24, 2006

County of Santa Cruz

HEALTH SERVICES AGENCY

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PUBLIC HEALTH DIVISION

May 24,2006

AGENDA: June 6,2006

BOARD OF SUPERVISORS
County of Santa Cruz
701 Ocean Street
Santa Cruz, CA 95060

Re: Report on Genetically Engineered Food Crops in Santa Cruz County

Dear Members of the Board:

On June 14, 2005, your Board created a subcommittee of the Public Health Commission to advise your Board on genetically modified crops. You also directed that the first task of this subcommittee be to conduct necessary research on whether the Board has the authority to adopt a moratorium on genetically modified crops, and whether it would be the recommendation that the Board do so.

It was also noted by the Health Services Agency that the overarching goal of the GE Subcommittee's eventual report was to educate and give recommendations to the Public Health Commission, the Board of Supervisors, and the community at large on genetically modified organisms and genetically engineered crops.

The purpose of this letter is to provide information on the work of the subcommittee over the past year, to respond to specific questions asked by the Board, and to make recommendations regarding the establishment of a moratorium, and to recommend further related actions.

Recombinant DNA technology and genetically engineered organisms have long been a concern in the County of Santa Cruz. In 1988, the Board of Supervisors unanimously approved Santa Cruz County Code, Title 7, Health and Safety, Chapter 7.30, "Noticing Requirements, Indemnification and Financial Assurances for the use of Recombinant DNA Technology" (see attached ordinance, Attachment A). The findings for this statute in Section 7.30.010 are still true today and provide a basis for these recommendations.

The Genetic Engineering (GE) subcommittee began meeting in August 2005 and limited its concerns to genetically engineered food crops. The subcommittee began by assessing the scope of the issue, investigating the regulatory/enforcement systems in place, researching the potential human, ecological, social, and economic impacts of genetically engineered (GE) crops in Santa Cruz County and have formulated recommendations based on its work.

Your Board requested the subcommittee to specifically focus on fourteen issues regarding genetic engineering. The Genetic Engineering Report developed by the GE Subcommittee (Attachment B) contains the full findings of the subcommittee in response to these objectives. A brief summary of each of these responses is also provided as an addendum to this letter, along with information on related state legislative actions and actions taken by other California counties.

Sumi of Findings

The GE Subcommittee identified the following as critical issues of concern for genetically engineered food crops. These issues have led the GE Subcommittee to recommend the countywide adoption of a Precautionary Moratorium:

- 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 was violating 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.

Subcommittee R : nmendations

The GE Subcommittee recommends that the County Board of Supervisors add a section, 7.30.090 to Chapter 7.30 of the Santa Cruz County Code that would establish a Precautionary Moratorium that would prohibit the planting and production of genetically engineered crops in Santa Cruz County.

It is recommended that this Precautionary Moratorium be lifted by the Board of Supervisors 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 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.

A minority of voting members presented a letter to the GE Subcommittee which is appended to this report as Attachment C for your information. Although the minority agree with all the conditions set forth by the GE Subcommittee that must be satisfied before introduction of GE crops should occur in Santa Cruz County, they disagree with the necessity of a precautionary moratorium and offer other options for consideration by your Board. In addition, a letter from Laura Tourte, the County Director and Farm Advisor is provided as Attachment D.

I would like to thank each member of the GE Subcommittee for sharing their time and expertise with County staff. Their thoughtful consideration of these issues is greatly appreciated.

It is, therefore, RECOMMENDED that your Board:

1. Accept and file this report on genetically engineered crops in Santa Cruz County;

2. Direct the Health Services Agency Director to work with County Counsel to amend Chapter 7.30 of the Santa Cruz County Code adding section 7.30.090 to establish a Precautionary Moratorium that would prohibit the planting and production of genetically engineered crops in Santa Cruz County and return to the Board for public hearing and final approval; and

3. Direct the Health Services Agency to share the Genetic Engineering Report with state and federal legislators and request that they take action to establish regulatory monitoring and oversight of genetically engineered crops, expand health and safety testing of the effects of exposure to genetically engineered organisms, expand the ability of farmers and the public to obtain legal recovery for damages caused by GE contamination, require GE labeling, and expand safeguards against GE contamination.

Sincerely,

Rama Khalsa

Rama Khalsa Ph.D.,
Health Services Agency Director

RECOMMENDED:

Susan A. Mauriello
County Administrative Officer

Attachments: Attachment A – Santa Cruz County Code Chapter 7.30
Attachment B – Genetic Engineering Report
Attachment C – Minority Letter

cc: County Administrative Office
Auditor-Controller
County Council
HSA Administration
Public Health Commission
GE Subcommittee

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Summary of Issues Regarding Genetic Engineering

Based on the Board's action of August 23 and directed objectives, the GE Subcommittee investigated and developed responses to the Board's fourteen objectives.

1. **Develop Definitions (reviewed San Luis Obispo's definitions but only addressed the definition of Genetically Engineered)**

   Genetic modification (GM) and genetic engineering (GE) are often used interchangeably in that both processes involve the alteration of an organism's genetic material. Genetic modification can involve alteration by conventional cross breeding or other historical methods. However, genetic engineering involves alteration by recombinant DNA technology. Recombinant deoxyribonucleic acid (rDNA) methods allow a gene from any species to be inserted into an organism's genetic material and subsequently expressed in a completely new food crop or other food product. Recombinant DNA technology allows such combinations that would not otherwise occur in nature.

   For example, researchers in Canada have inserted a frog gene into potato plants to make them produce a chemical that protects the genetically engineered potato from a broad range of infections caused by fungi and bacteria. This GE potato is still in research phase and is not commercially available.

   The subcommittee reviewed the definitions contained in the San Luis Obispo County's report on genetically engineered organisms and decided that only the definition of genetically engineered organisms, as defined in the preceding paragraph, was crucial to be contained in the County of Santa Cruz' report. The Santa Cruz County report attempts to avoid the use of scientific terminology for ease of understanding.

2. **What is occurring now and what is the potential for Genetically Engineered (GE) crops and crop applications in Santa Cruz County?**

   The planting of GE crops is not required to be publicly disclosed to any federal, state or county agency.

   Therefore, the GE Subcommittee has no way of knowing the types of GE crops that are grown in Santa Cruz County. The potential for GE test crops to be grown in Santa Cruz County is discussed in objective number 3.

3. **What kind of GE research is being conducted in the county that has the potential to contaminate nearby crops and neighborhoods?**

   GE research is currently being performed on a number of crops that are routinely grown in Santa Cruz County, including our high value crops of strawberries, raspberries, broccoli, lettuce, apples, and various ornamental flowers. GE research is also being conducted on other crops that are grown in Santa Cruz County such as cucumbers, onions, peas, peppers, pumpkins, grapes, squash, sweet corn, tomatoes, avocados, persimmons, plum, and walnuts. Although we know that this research is being conducted in California, we do not know whether any such research is being conducted in Santa Cruz County at this time. (See Appendix 4, page 46 and page 18 of the GE Subcommittee Report).

In California, 1,203 field tests have taken place since the inception of the United States Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) field test program in 1987 in undisclosed locations. Between January 1 and September 28, 2005, alone, 75 field tests have been conducted across the state in undisclosed locations.

Our GE Subcommittee filed seven Freedom of Information (FOIA) requests pertaining to Santa Cruz and the surrounding counties, and only one was answered. It stated that: the APHIS was "unable to locate records responsive to your request" about whether GE field tests were conducted in Santa Cruz County between 2004 and 2005.

Therefore, despite active research and investigation, the GE Subcommittee is unable to say with certainty that past or present GE field tests have been conducted in Santa Cruz County. (A full discussion of the GE Subcommittee's FOIA research is discussed on page 18 of the GE Subcommittee Report.)

4. **Are there field trials of pharmaceutical crops being conducted in open fields in the county, and if so, how can the County ensure proper protection of public health and the food supply from contamination that may result from such trials?**

   We have no definitive way to determine whether GE field trials of pharmaceutical crops are being conducted in open fields in our county. There is currently no methodology or technology that could ensure proper protection of public health and the food supply from contamination that may result from such trials.

5. **What types of tracking mechanisms are in place for monitoring research of GE crops and their discards?**

   APHIS is charged with permitting and monitoring research of GE crops and their discards. However, according to the findings of a report released by USDA's Inspector General, in December 2005, 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.

   The USDA 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 GE crops from persisting in the environment outside the field test site. APHIS also does not effectively track required field test site information, including the permit holder's progress report, the results of field tests or any harmful effects on the environment discovered during the tests. Approved applicants sometimes let harvested crops lie in the field test site for months, allowing GE test seeds to be scattered by the rain, wind, animals, birds, and insects. (See page 12 of the GE Subcommittee Report)

6. **What type of notification procedures exists to inform nearby residents and farmers of the intent to plant a GE commercial or "test" crop?**

   There is no required notification of nearby residents or farmers of the intent to plant a GE commercial or "test" crop.

7. **What are the potential impacts on organically and conventionally grown local produce?**

   GE contamination could potentially cause a loss in crop market prices, rejection of food crops by domestic or international buyers, a loss of market reputation, and a loss of organic certification and registration.

The contamination issue is further complicated by the absence of laws designed to assess liabilities for any issues of GE contamination. **A** plaintiff may be able to seek damages from a defendant in a civil lawsuit based on tort law. In some instances, the cost of destroying a GE-contaminated food product has been borne by taxpayers.

8. What are the issues for both producers and consumers?

Issues for consumers: currently, no labeling regulations exist for foods containing GE ingredients. This eliminates choice for consumers. No long-term human health studies have been conducted on the consumption of GE food. There are published reports of multiple, deleterious health effects on immune systems and fertility of lab animals fed GE foods. Scientists have expressed concern about the creation of new allergenic toxins, carcinogens, and novel infectious diseases from the consumption of GE foods. **(A** full discussion of the health impacts is presented on pp. 29-31 of the GE Subcommittee Report).

Issues for producers: see objective number 7.

9. What are the potential ecological, economic and social impacts from GE production?

The full impact of GE crops on the natural environment is hard to assess. Some of the ecological risks include genetic pollution and the gene flow of GE traits to non-GE crops and wild, weedy relatives, escape of GE organisms into the environment, non-target kills of beneficial insects, and loss of biodiversity. **(A** full discussion of the ecological impacts is presented on pp. 24-28 of the GE Subcommittee Report).

Several studies contend that higher yields or decreased pesticide use (or both) translate into higher profitability for farmers growing GE crops. However, the loss of markets due to consumer rejection of GE contaminated crops is another potential economic impact. **(A** full discussion of the economic impacts of GE is presented on pages 19-23 of the GE Subcommittee Report).

GE reinforces trends towards the consolidation of the agriculture supply sector by a few firms, which ultimately leads to the loss of small and mid-scale farms. **(A** full discussion of the social impacts is presented on pp. 36-39 of the GE Subcommittee Report).

10. What are the security/privacy issues that affect producers and the public?

Planting of GE field trials and deregulated GE crops is not required to be disclosed by law. This protects the producer but leaves the public unable to protect themselves from the potential risks of GE contamination. Labeling of GE foods is not required by law. This eliminates consumer choice about whether or not they purchase or eat GE foods.

11. How can residents and farmers protect their farms and gardens from GE contamination?

There is no guaranteed way to protect against GE contamination. The movement of pollen and seed by natural pollinators, wind, and human error in planting, field clean-up, transportation, and food processing all pose considerable risks. Buffering with forests or other landscape obstacles is not a deterrent that can be relied upon with any certainty.

12. Analysis of existing regulations – County, State and Federal.

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). 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. The EPA is responsible for regulating pesticides under the Federal Insecticide, Fungicide and Rodenticide Act. USDA's Animal and Plant Health Inspection Service (APHIS) is responsible for preventing the importation and interstate dissemination of plant pests and noxious weeds.

The GE Subcommittee analyzed this regulatory framework and their findings were consistent with the USDA's Office of Inspector General audit, conducted from May 2003 to April 2005 and consisted of visits to 91 field test sites and review of records. This report issued a finding that "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." According to the report, APHIS "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." (See page 9 of the GE Subcommittee Report).

The California Department of Food and Agriculture (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 summary, there is no effective regulatory oversight at the state and federal levels.

13. What types of liability provisions exist to protect farmers, both conventional and organic, if their crops become contaminated with GE organisms?

To our knowledge there are no statutes containing liability provisions protecting farmers if their crops become contaminated with GE organisms. There have been cases of farmers being sued by the GE seed company, Monsanto, for patent infringement under many different circumstances.

14. What types of legal remedies are available to protect farmers from lawsuits resulting from unwanted contamination of their crops and subsequent claims of patent infringement?

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.

Status of GE Actions in Other California Counties and State

As of March 6, 2006, three counties (Mendocino, Trinity, and Marin) have passed anti-GE ordinances, four counties (Humboldt, Butte, Sonoma and San Luis Obispo) have rejected anti-GE ordinances, eleven counties (Siskiyou, Lake, Napa, Yolo, Nevada, Placer, Sacramento,

Contra Costa, San Francisco, Alameda, and Santa Barbara) are currently considering anti-GE ordinances, and twelve counties (Sutter, Solano, San Joaquin, Stanislaus, Merced, San Benito, Madera, Fresno, Kings, Tulare, Kern, Imperial) have passed pro-GE resolutions. At the State Legislature there were two bills addressing GE, AB 984, John Laird and SB 1056 Dean Florez. To date, both bills have been amended to address non-GE issues. AB 984 has been amended to authorize a program for the control and/or eradication of tamarisk in the Colorado River basin. SB 1056 has been amended to address air quality and agricultural burning, especially in regards to incentives for reduced agricultural air pollution.

Chapter 7.30

NOTICING REQUIREMENTS, INDEMNIFICATION AND FINANCIAL ASSURANCES FOR THE USE OF RECOMBINANT DNA TECHNOLOGY

Sections:

7.30.010	**Findings.**
7.30.020	**Purpose.**
7.30.030	**Applicability.**
7.30.040	**Definitions.**
7.30.050	**Notice.**
7.30.060	**Indemnification and financial assurances.**
7.30.070	**Enforcement.**
7.30.080	**Severability.**

7.30.010 Findings.

A. Uses of recombinant DNA processes involving the release of genetically engineered organisms into the open environment may pose risks to public health, safety and the environment not adequately addressed under current federal and state regulations.

B. While the control of the release of genetically engineered organisms into the environment may generally be considered the responsibility of federal and state governments, it is local government that may initially be called upon to respond to any adverse effects on public health, safety and the environment, resulting from the release of such organisms into the open environment.

C. In order for local government to have the capacity to provide appropriate response in such instances, it is, at minimum, necessary for local government to have notice of all uses of recombinant DNA technology and the genetically engineered organisms created by the recombinant DNA process which have not been approved by either the state or federal government for use in the manner and for the purposes now proposed.

D. In order to protect the public health, safety and the environment, it is in the public interest for local government to establish rules and requirements for such activity involving recombinant DNA technology. (Ord. **3904** § 1 (part), **1988)**

7.30.020 Purpose.

The purpose of this chapter is to establish policy, standards and requirements pertaining to the use of recombinant DNA technology so that public health and safety and the environment be afforded the maximum degree of protection. It is not the intent of this chapter to enter the regulatory sphere occupied by federal and/or California State Government; rather, it is the intent of this chapter to more fully carry out the county's health and safety authority in areas not presently covered by state or federal law or regulation. (Ord. **3904** § 1 (part), **1988)**

7.30.030 Applicability.

This chapter is applicable to the use of recombinant DNA technology, the use of genetically engineered organisms created by the recombinant DNA process, or the use of any product created thereby, within the unincorporated portions of the county of Santa Cruz subject to the following exceptions:

A. Any use of any "economic poison" as defined in Section 11501.1 of the California Food and Agricultural Code, and certified by the California Department of Food and Agriculture for its use, experimental or otherwise, in the manner and for the purposes now proposed.

B. Any use of recombinant DNA technology, genetically engineered organisms created by the rDNA process, or products created thereby, duly given final approval and certified by the federal and/or California State Government for its use (experimental or otherwise) in the manner and for the purposes now proposed. (Ord. **3904** § 1 (part), **1988)**

7.30.040 Definitions.

For the purposes of this chapter, unless the context otherwise indicates, certain words and phrases used in this chapter are defined as follows:

A. "DNA" means deoxyribonucleic acid.

B. "Genetically engineered organisms" means organisms including bacteria, fungi, protozoa and viruses, created or modified by recombinant (rDNA) technology. It does not include nonliving or nonreproducing organisms or products.

C. "Genetic engineering" means a process or technology employed whereby the hereditary apparatus of a living cell is altered, modified or changed so that the cell can produce more or different chemicals or perform completely new functions.

D. "Open environment" means an area outside a particular sealed environment in which the subject rDNA material is contained.

E. "Person" means any individual, firm, partnership, trust, corporation, company, estate, public or private institution, association, organization or group, and any representative, officer, employee or agent of any of the foregoing.

F. "Recombinant DNA (rDNA)" means molecules that:

1. Consist of different segments of deoxyribonucleic acid (natural or synthetic) that have been joined together in an environment outside any cell or cellular organisms and which have the capacity to replicate in some host cell either autonomously or after they have been integrated into the host cell's geonome; or

2. Are the result of a replication of the DNA molecules described in subsection F1 of this section.

G. "Use of recombinant DNA technology" or "DNA technology" means an activity, either commercial or noncommercial, undertaken by any person to use recombinant DNA for any purpose, including but not limited to the creation of a product or by-product of genetically engineered organisms, when that use involves the entrance of recombinant DNA into the host cell or the packaging of such DNA into a vector capable of effecting such an entrance.

H. "Release" means to discharge, emit or liberate any genetically engineered organism, or the product of a genetically engineered organism, created by the recombinant DNA process into the open environment. (Ord. 3904 § 1 (part), 1988)

7.30.050 Notice.

A. No person shall make nonexempt use of rDNA technology within the unincorporated portions of the county of Santa Cruz, without first providing notice at least ninety days in advance of such activity to both the county health officer and the clerk of the board of supervisors of the county of Santa Cruz.

B. The required notice shall include the following information:

1. The name, mailing and office address, telephone number, and authority of the person submitting the notice.

2. A complete description of the proposed rDNA technology activity. (Ord. 3904 § 1 (part), 1988)

7.30.060 Indemnification and financial assurances.

A. The person proposing each and every nonexempt use of rDNA technology shall indemnify and hold harmless the county and its officers, agents and employees from actions or claims of any description brought on account of any injury or damages sustained (including death) by any person or property resulting from the proposed rDNA activity.

B. The person proposing each and every nonexempt use of rDNA technology shall provide financial assurances that are adequate to respond to damage claims arising from such use. Such financial assurances shall be in the form of a trust fund, surety bond, letter of credit, insurance or other equivalent financial arrangement in a form determined to be satisfactory by the county, and shall be in an amount determined to be satisfactory by the county. (Ord. 3904 § 1 (part), 1988)

7.30.070 Enforcement.

A. It shall be the duty of the health officer of the county of Santa Cruz to enforce this chapter, and all designated officers and employees of the county department are charged with the enforcement of this chapter and each and every provision thereof.

B. Any person, whether as principal or agent, employee or otherwise, violating or causing or permitting the violation of any of the provisions of this chapter, shall be guilty of a misdemeanor, and upon conviction thereof, shall be punishable by a fine of not more than one thousand dollars or by imprisonment in the county jail of the county of a term not exceeding six months or by both such fine and imprisonment. Such person, agency, firm or corporation shall be deemed to be guilty of a separate offense for each day during any portion of which any violation of this chapter is committed, continued or permitted by such person and shall be punishable as herein provided.

C. Any building or structure set up, erected, constructed, altered, enlarged, converted, moved or maintained, contrary to the provisions of this chapter, and/or any use of the land, building or premises, established, conducted, operated or maintained contrary to the provisions of this chapter, shall be, and the same is declared to be a violation of this chapter and a public nuisance.

D. The county may summarily abate, or abate pursuant to Chapter 1.14 of this code, any public nuisance and the county counsel or the district attorney, upon order of the board of supervisors, may bring civil suit, or other action, to enjoin or abate the nuisance.

E. Each day any violation of this chapter continues shall be regarded as a new and separate offense. The remedies provided in this chapter shall be cumulative and not exclusive.

F. Any person who creates or maintains a public nuisance in violation of this chapter shall be liable for the costs of abatement which shall include, but not be limited to:

1. Costs of investigation;

2. Costs of removing genetically engineered organisms from the open environment, cleanup and restoration of the environment;

3. Cost of county employee enforcement time;

4. court costs;

5. Costs of monitoring compliance.

G. Should any person violate the terms of this chapter and any action be authorized by the board of supervisors, either by the county counsel, or the district attorney, or be in fact filed by either or both of such agencies for the violation, no other action shall be taken on any application filed by or on behalf of such person until the violation has been resolved, or such application is denied or conditionally approved. (Ord. 3904 § 1 (part), 1988)

7.30.080 Severability.

The provisions **of** this chapter are severable. If any section, paragraph, sentence, phrase or word of this chapter is declared invalid for any reason, that decision shall not affect any other portion of this chapter, which shall remain in full force and effect. (Ord. 3904 § 1 (part), 1988)

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PUBLIC HEALTH DIVISION

County of Santa Cruz

HEALTH SERVICES AGENCY

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(831) 454-4000 FAX: (831) 454-4488 TDD: (831) 454-4123

Genetic Engineering (GE)

A Report from the GE Subcommittee of
The Public Health Commission
May, 2006

Laurie Howard	1st District	*	Richard Nutter	4th District
Katherine Sweet	1st District	*	Arty Mangan	5th District
Ken Kimes	2nd District	*	Wesley Van Camp	5th District
Steve Bontadelli	2nd District	*	David Moeller	Agricultural Commissioner
Phil Howard	3rd District	*	Matt Farrell	Public Health Commission
Lisa Bunin	3rd District	*	Poki Namkung	Health Service Agency
Thomas Rider	4th District	*	Laura Tourte	Ex-Officio (non-voting) UC Cooperative Extension

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). Since the Bt toxin is contained in every cell of the plant, pests die when they eat the plant. 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 also have been genetically engineered to produce experimental veterinary vaccines to prevent pig diarrhea and other 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.

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 onward submission to the Santa Cruz County Board of Supervisors.

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[1] Osusky, M., Osuska, L., Kay, W., Santosh, M. (2005) "Genetic modification of potato against microbial diseases: in vitro and in planta 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

The detailed research embodied in this report has led the GE Subcommittee to recommend to the Board of Supervisors that it add a section, 7.30.090 to Chapter 7.30 of the Santa Cruz County Code' The recommended section would establish a Precautionary Moratorium on growing 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 USDAs 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.

In light of this and other significant findings contained in the report, the GE Subcommittee recommends that the County Board of Supervisors add a section, 7.30.090 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.

The GE Subcommittee recommends that a Precautionary Moratorium be established that would prohibit the planting and production of genetically engineered crops in Santa Cruz County. It is

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

recommended that this Precautionary Moratorium be lifted by the Board of Supervisors 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 on 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, 7.30.090 to Chapter 7.30 of the Santa Cruz County Code that would establish a Precautionary Moratorium on 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.

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.

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.

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

United States Department of Agriculture (USDA)
USDAs 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' 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 'Yhat 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?
- 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/fieldtestsl .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] [7] Spector; Lee and Lau; Nestle, p. 209
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.'

- 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?

- 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.' 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.*.

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 USDAs 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 USDAs 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 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.

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[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

The StarLink contamination case provides the most well-known incident of GE contamination of the food supply.' The USEPA did not approve StarLink's GE corn (containing a 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.*

ATTACHMENT B

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. June2001	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.*

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.

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[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/fieldtestsl.cfm.

AITACHMENT B

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	153	16%	38	34%
Cotton	84	7%	6	5%
Rice	82	7%	5	6%
Melon	72	6%	0	0 X
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%

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.

AITACHMENT B

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 USDAs 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'. 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 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.

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[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, subcommitteemember 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.'

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 cucumber, onion, peas, pepper, pumpkin, grapes, squash, sweet corn, tomato, avocado, persimmon, plum, and walnut.

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.'

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-organictransition 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 cost for organic growers who lose certification

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.

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 can not assess GE horticultural crop productivity at this time.'

[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/troubled_times.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 were not 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

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[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'.' 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 Btcrops 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.' 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. 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 is 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 a/,* 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 yea: and the effect it has on soil species and microorganisms has the potential to be ecologically damaging. 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.'

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: 1) Targeted quantitative analysis that quantifies a predetermined compound or class of compounds, e.g. assessment of nutritional components such as saturated fat; and 2) 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 accompany 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.

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. Say, for example, a class action suit 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.* 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, a an estimated rate of 500 or more every year'. 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.' 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** for 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 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.'

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." 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."[1]

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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 1930s. 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.[2]

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."[3] Moreover, America's farming communities now suffer some of the highest rates of hunger and poverty in the nation.[4] 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.[5]

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.[6] The capital-intensive nature of GE crops is one of such innovations that is likely to increase input costs for farmers[7].

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.[8]

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.[9]

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[1] In the current political economic system, corporations prefer this to a monopoly because it attracts less attention from regulators (Zachary 1999).
[2] Manjula 2000
[3] Ibid
[4] Altieri 2005
[5] Goldschmidt 1946, Lobao 1990, Lyson et a1. 2001
[6] Cochrane 1958, Levins & Cochrane 1986
[7] Benbrook 2002
[8] Howard2003
[9] 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.' 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?

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

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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.

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[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?

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? 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, that was 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

ATTACHMENT B

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

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 CryIAb	Monsanto 524-492	May, 1996	**Voluntarily cancelle** 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 cancelle** October, 2000
Replicase for potato leaf roll	Monsanto 524-474	November, 1998	No expiration date
Bt corn POCryl F	Dow/Mycogen 68467-2	May 2001	October 15, 2008
Bt corn poCry1 F	Pioneer/Dupont 29964-3	May 2001	October 15, 2008
Bt cotton Cry2Ab2 in combo with CryIAc	Monsanto 524-522	December 2002	September 30,2006
Bt corn Cry3Bb1	Monsanto 524-528	February, 2003	July 31, 2006
Bt corn stack Cry3Bb1 + CryI Ab	Monsanto 524-545	October 31, 2003	July 31, 2006
Bt cotton CryIAc + CryI F (WideStrike)	Dow AgroSciences 68467-3	September 30,2004	September 30, 2009
Bt corn MOCry1 F 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 POCryl F	Dow AgroSciences 68467-6	October 27,2005	October 15, 2008
Bt corn Cry34Ab1 + Cr35Ab1 with POCryl F	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 + CryIA	Monsanto 524-552	December 13,2005	October 15, 2008

Regulatory Aaencies Unified Biotechnoloav

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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 €or 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, Hancack 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.

Signacure _____ Date _____
Name Typed _____

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Return to Biotechnology Home Page

ATTACHMENT B

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 cbunin@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

ited 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
Past 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

Crop	*Deregulated Commercialized*	*2005 Field Test Release Permits-APHIS #*	*Research and Case Study Stage*
References	www.nbiap.vt.edu	www.isb.vt.edu	www.nctap.org
Blackberries			
Raspberries			Case Study
Strawberries			Case Study
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

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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

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Appendix 5

Other Countries' Requirements for GE Crops and Dates Enacted'

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/pubsNVorld%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

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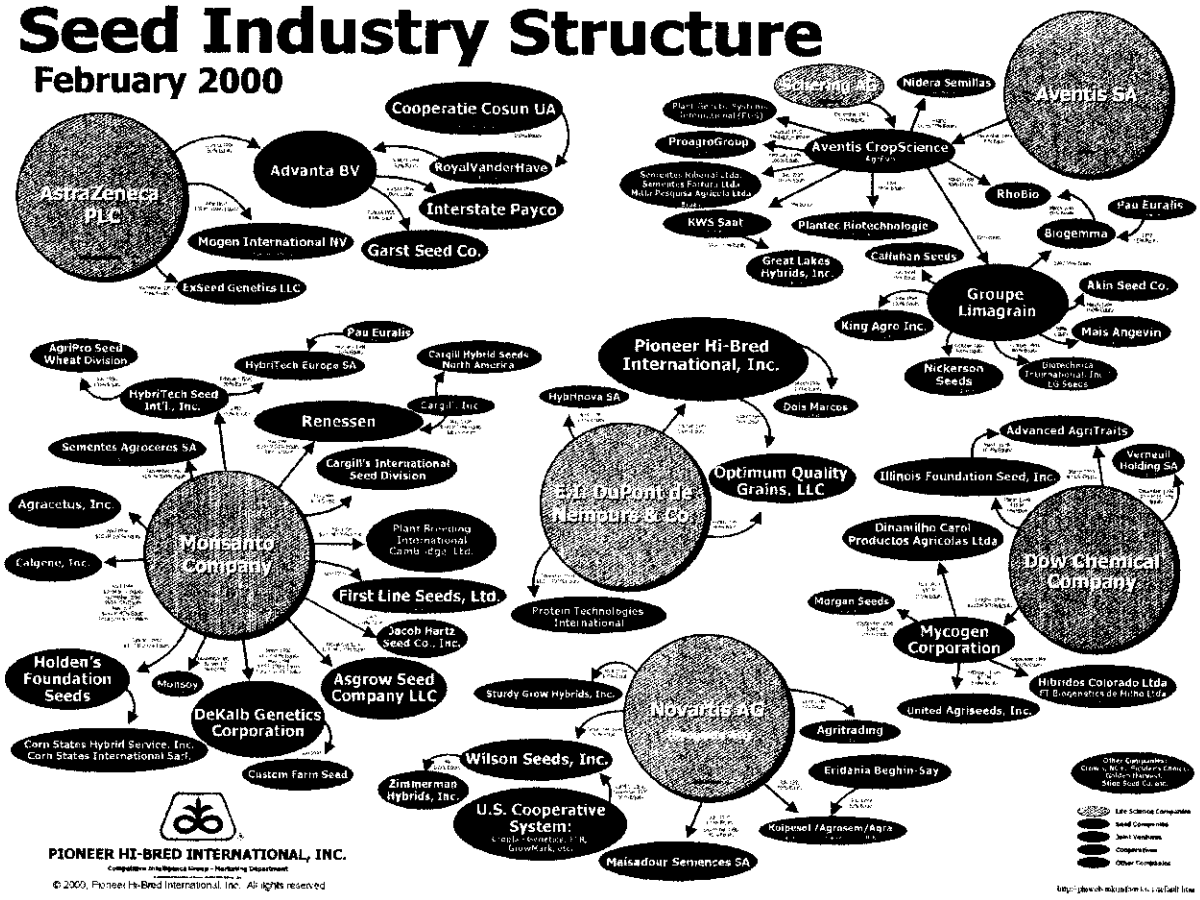
Appendix 7



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.

Appendix 7

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MINORITY LETTER – ATTACHMENT C

GE SUBCOMMITTEE

MINORITY REPORT ON RESPONSE TO BOARD OF SUPERVISORS

We are Subcommittee members who disagree with the majority regarding the presentation to your Board of a proposed precautionary moratorium on the planting and production of GE crops in Santa Cruz County, to the exclusion of any other alternatives

After many months of meetings including hours of discussions on the merits of the collected research data, it is clear to us that there are other options that should be presented to the Board for consideration.

Recognizing that science has been dynamic and innovative in keeping the agricultural industry competitive and profitable we do not believe there is supporting evidence to justify intervention at the local level.

The minority believes this technology holds promise, and we do not want to close the door on those opportunities for increased yields, reduced pesticide use and reduced tillage, which results in cleaner water and air through reduced emissions and soil erosion. If the Board of Supervisors wishes to impose heavier restrictions on biotech crops, we ask the Board to allow protections for those that could potentially benefit from this technology, by implementing reasonable, achievable access to biotech crops.

Although there is GE research being conducted on various crops that are also grown in Santa Cruz County, there are no biotech crops on the marketplace that would immediately impact our farming community. In California, most biotech crop production to date has been limited to only three crops: cotton, corn and alfalfa. Most biotech research is not financially conducive for fruits and vegetables therefore any potential production in biotech specialty crops is unlikely to impact the immediate future of Santa Cruz County.

We believe the Board of Supervisors should have more than one option in deciding this important issue. Therefore, we offer the following options for the Board's consideration:

1) Take no action: There is no known interest by production agriculture to plant GE crops in Santa Cruz County at this time.

2) Request that legislators seek funding at the state and national level to provide for enforcement of existing regulations. This could be by Resolution of the Board.

3. Table the issue for the time being until more information is available, as this is an emerging industry that is not currently threatening the health or safety of the citizens of Santa Cruz County.

4. Create a biotech crop "clearing house" with the Agricultural Commissioner's office. If GE crops are grown in Santa Cruz County, the type and location of GE crops grown and tested in Santa Cruz County shall be communicated to the Agricultural Commissioner prior to planting, and the information made available to the public upon request. This would allow for any potentially affected growers to make adjustments and/or agreements with their neighbors when making planting decisions.

5. Amend Chapter 7.30 of the Santa Cruz County Code, to include the suggested language of the subcommittee's precautionary moratorium. This law has been in effect since 1988.

- Field trials of genetically engineered crops are contained to prevent contamination of organic and non-GE crops and weedy relatives.
- 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.
- 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.
- GE seeds and root-stock shall be labeled so that farmers and gardeners can choose whether or not they want to grow GE crops.
- 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.

In summary, we feel that there should be more than one option available to the Board in making their decision on how to address the GE issue as it pertains to Santa Cruz County.

UNIVERSITY *of* CALIFORNIA
Agriculture & Natural Resources
COOPERATIVE EXTENSION • SANTA CRUZ COUNTY
1432 Freedom Boulevard • Watsonville, CA 95076-2741
Tel (831) 763-8040 Fax (831) 763-8006 E-Mail cesantacruz@ucdavis.edu

May 26,2006

Board of Supervisors
County of Santa Cruz
701 Ocean Street
Santa Cruz, CA 95060

Re: GE Subcommittee – June 6,2006 Board Meeting

Honorable Members of the Board:

In August 2005 I was asked by your Board to serve on the County's Genetic Engineering (GE) subcommittee. The University of California Cooperative Extension (UCCE) is an organization dedicated to providing science and research-based information and education to the local communities it serves. UCCE's three significant program areas are agriculture, natural, and human resources. It is not within the purview of our organization to advocate for a position or make policy recommendations. However, with respect to important community issues, we do provide research-based information to inform government and policy processes.

The topic of GE is multifaceted and complicated. Indeed, scientists and researchers devote entire careers to the subject. My role within the GE subcommittee was as an information provider and a non-voting member. During the committee's tenure, in the time available for preparing the GE subcommittee report, I tried to provide general indicators of the available research, including a discussion of the potential risks, costs, and benefits of GE, as well as unanswered research questions. Because my background is in small farm economics and marketing, I was glad to work with others to research aspects of the economics associated with GE. We provided a summary of available research for the subcommittee report.

The GE subcommittee report is being submitted to your Board for discussion at the June 6th, 2006 Board meeting. I am unable to attend the June 6th Board meeting to respond to questions because of a scheduling conflict; however, I wanted to take this opportunity to again emphasize that my role as a part of the subcommittee was solely to provide information. I am glad to have been able to help on this issue, but want to make clear that I had no input to the recommendations provided in the report.

Ultimately, the use of agricultural biotechnology (GE) and its relevance for Santa Cruz County is a public policy issue that includes aspects of science, public perception, and societal values. Given these myriad conditions, there can sometimes be a 'gray area' between those values and interpretation of research results and facts. I believe that careful thought, along with an evaluation of all available information can lead to creative, inclusive decisions that have merit for the entire community in both the short and long-term.

I would be glad to respond to questions you might have, or provide you with additional information.

Sincerely,

Laura Tourte
County Director and Farm Advisor

Cc: Refugio Gonzalez, ANR-UCCE Regional Director

Copy To Each Supervisor

Feeding the Future

June 1,2006

Mark W. Stone, Supervisor
County of Santa Cruz
701 Ocean Street, Room 500
Santa Cruz, CA 95060

Dear Supervisor Stone:

While the fundamentals of farming are well known, the actual practice of growing and ranching in California has undergone much change and innovation. Access to biotechnology will allow California family farmers to continue the course of being the most progressive farming community in the United States, and play a vital role in providing safe and healthy food throughout the world.

All consumers benefit from high-quality products. Therefore, we all have a vested interest in protecting California's agriculture. California's farmers and ranchers provide the safest and most affordable food anywhere, which allows the high quality of life in your community.

To meet growing consumer needs while caring for the environment, farmers must produce more food on less land. Biotechnology, otherwise known as biotech crops, will play a key role in achieving this goal.

To share the benefits of biotech crops with California consumers, a diverse group of farming and business interests formed the California Healthy Foods Coalition. As a service, we are available to you should you have any questions related to this proven science. We encourage you to study the enclosed brochure, visit our website and call Emily Robidart at (916) 561-5634 if you have any questions.

Together, we can protect California's family farmers, local jobs and our children's promise of a healthy future.

Sincerely,

DOUG MOSEBAR
President
California Farm Bureau Federation

PS: Visit our website to find out why over 15 counties have passed resolutions endorsing the science of biotech crops.

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What is Biotechnology?

Agricultural biotechnology is a collection of techniques, including genetic engineering, to improve plants and to enhance the environment on farms. Through genetic engineering, scientists are able to cut and paste desirable genes from one molecule of DNA to another. This practice technology allows for the transfer of specific, desirable genes, unlike traditional crossbreeding which transfers a whole host of genes, including unwanted ones.

Biotech crops have proven to be beneficial to the environment and offer great promise for future generations. With continued advances in agricultural technology, today's farmer is far more effective in meeting the expectations of modern consumers.

CALIFORNIA HEALTHY FOODS COALITION

Feeding the Future

CA Healthy Foods Coalition
P.O. Box 15481 • Sacramento, CA 95851
phone 916-561-5634 • fax 916-561-5693
info@feedingthefuture.org
www.feedingthefuture.org

CALIFORNIA HEALTHY FOODS COALITION

Feeding the Future

How Biotechnology Plays a Vital Role in Providing Safe and Healthy Food

Producing Safe & Healthy Food

Agricultural advancements have improved the quality of many foods American consumers have been enjoying for more than 20 years.

Providing for Our Future

Agricultural land is rapidly becoming scarcer as land is lost to urban development. This requires future farming to be as resourceful as it is rewarding. With an eye to the future, today's family farmers have embraced the science of biotechnology. They are planting for America's future.

Enhancing the Environment

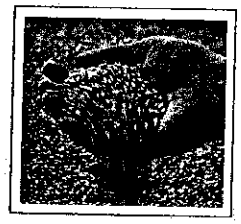
Biotech crops require the application of fewer crop protection materials, which decreases the time a tractor drives through a field. Therefore, biotech crops:

- Improve air quality by reducing diesel emissions
- Advance water quality by decreasing soil compaction
- Encourage water conservation by lessening the amount of airborne dust particles which cuts the amount of water used to keep the dust down.

Protecting the Wilderness & Open Space

With the world's population significantly on the rise, and increasing pressures from urbanization, California farmers need to produce more food on less land. Biotechnology has the potential to preserve our family farms and remaining wilderness by making existing farmland even more productive.

How Do We Know Biotech Crops are Safe?



All biotech products on the marketplace today have gone through seven to 10 years of scientific testing and review, and millions of dollars in research. These products have been thoroughly reviewed by scientists working for the U.S. Environmental Protection Agency, the U.S. Department of Agriculture and/or the Food and Drug Administration. Those agencies review and approve crops on a case-by-case basis.

Endorsements

Numerous scientific and health organizations around the world agree that biotech crops present no unique safety risks when compared to other crops. Here is a sample of the organizations that have endorsed the use of biotech crops:

- U.S. National Academy of Sciences
- American Medical Association
- United Nations, Food and Agricultural Organization
- World Health Organization

In the Pipeline

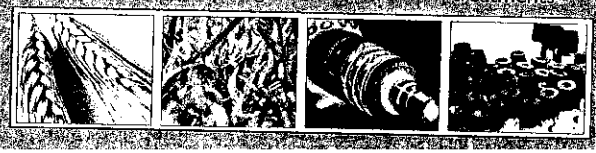
Hypoallergenic wheat

Slow-Grow or No-Mow grass

Green algae

Energy Farms

Cancer treatments



Thank You for Your Support!

Your support will assist us in increasing our outreach efforts by further educating the public about the benefits of biotechnology.

Name

E-mail

Address

City/State/Zip

Phone

Occupation

Volunteer Roles:

- ☐ Host an event
- ☐ Speaker
- ☐ Letters to the editor
- ☐ Link my website to CHFC
- ☐ Recruit volunteers
- ☐ Media relations
- ☐ Fund-raising
- ☐ Other

Interests:

- ☐ Farming
- ☐ Environment
- ☐ Education
- ☐ Health
- ☐ Jobs
- ☐ Other

☐ **Please e-mail me the *Feeding the Future* Newsletter.**

CA Healthy Foods Coalition
P.O. Box 15481 • Sacramento, CA 95851
phone 916-561-5634 • fax 916-561-5693
info@feedingthefuture.org
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CALIFORNIA HEALTHY FOODS COALITION

Feeding the Future

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CA Healthy Foods Coalition
P.O. Box 15481
Sacramento, CA 95851-9958

CBD BOSMAIL

From: CBD BOSMAIL
Sent: Monday, June 05, 2006 3:23 PM
To: CBD BOSMAIL
Subject: Agenda Comments

Meeting Date : 6/6/2006

Item Number : 58

Name : Linda Brodman

Email : Not Supplied

Address : 1231 Andrew Street
Santa Cruz, CA 95062

Phone : Not Supplied

Comments :
I support the GE Subcommittee recommendations to the County Board of Supervisors which recommends a Precautionary Moratorium that would prohibit the planting and production of genetically engineered crops in Santa Cruz County.

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CBD BOSMAIL

From: CBD BOSMAIL
Sent: Monday, June 05, 2006 12:00 PM
To: CBD BOSMAIL
Subject: Agenda Comments

Meeting Date : 6/6/2006

Item Number : 58

Name : Peggy Miars

Email : peggy@ccof.org

Address : Executive Director, CCOF, 1115 Mission Street, Santa Cruz, CA 95060

Phone : 423-2263

Comments :
Hello. I urge you to adopt a precautionary moratorium on the growing of GE crops in Santa Cruz County.

I'm Peggy Miars, Executive Director of California Certified Organic Farmers (CCOF). CCOF represents nearly 1,400 certified organic producers and 300 supporting members, including 112 members and certified companies in Santa Cruz County.

For years, CCOF has opposed the commercialization of GE crops. We worked to ensure that the USDA's National Organic Program standards classify genetically modified products as an excluded method in organic production.

There are many unanswered questions about the effects that genetic engineering could have on the health and ecology of our world once released into the environment. Our concerns include:
1) The impact of GE crops on beneficial insects and other non-target species
2) Pests resistant to herbicides are likely to develop with GE agriculture
3) Genetic pollution is already affecting organic and non-organic farmers and causing economic harm.
4) The effects of GE crops on human health is unknown because adequate testing and studies have not been done.
5) Increased costs and liability to organic and non-organic farmers.

CCOF supports a moratorium on the open field propagation of GE crops until:
1) Adequate, accurate, peer-reviewed research assessing the risks GE crops pose to wildlife, human health, and soil ecology is required to be presented as part of the approval process for any proposed commercialization.
2) Contamination of organic and non-organic crops by GE crops is the liability of the patent owners and growers of these GE crops.
3) An adequate regulatory framework is in place to protect organic and non-organic farmers from GE contamination at all stages of the farming process, including labeling standards and

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requirements to identify GE content during all phases of the farming process, but most especially on final product presented to consumers.

Thank you for your time and consideration.

CBD BOSMAIL

From: CBD BOSMAIL
Sent: Friday, June 02, 2006 2:14 PM
To: CBD BOSMAIL
Subject: Agenda Comments

Meeting Date : 6/6/2006

Item Number : 58

Name : Karin Grobe

Email : kgrobe@pacbell.net

Address : 236 Sheldon Ave.
Santa Cruz, CA 95060

Phone : 831-427-3452

Comments :
Please establish a precautionary moratorium on the use of gentically engineered crops in Santa Cruz County. Organic farming is an important, growing industry in the county and genetically engineered crops could escape and contaminate organic crops.

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CBD BOSMAIL

From: CBD BOSMAIL
Sent: Saturday, June 03, 2006 11:10 AM
To: CBD BOSMAIL
Subject: Agenda Comments

Meeting Date : 6/6/2006

Item Number : 58

Name :jane freedman

Email : bellasbestt@yahoo.com

Address : **14** blake ave corralitos cal 95076

Phone : **831 566 2604**

Comments :
please take all measures about this issue very seriously. I am an organic farmer I dom not use genetically modified seeds because they get into the gene pool of all creatures great and small ,. Altering the balance within an ecosystem and those humans that eat these ,supposedly enhanced crops. fish have 3 eyes and frogs no legs. there are alot of studies, I am sure you are all abreast of the situation. I am deeply concerned about the companies that feel the need to promote this kind of biological warfare. we are at the stage here in the county where we can be leaders for the country. please take precaution sssstop gmos. in our beautiful county thanks

CBD BOSMAIL

From: CBD BOSMAIL
Sent: Monday, June 05,2006 9:48 AM
To: CBD BOSMAIL
Subject: Agenda Comments

Meeting Date : 6/6/2006

Item Number : 58

Name : Sam Earnshaw

Email : sambo@cruzio.com

Address : 602 Delta Way
Watsonville, CA 95076

Phone : 831 722-5556

Comments :
June 5,2006

Comment on GMO Moratorium in Santa Cruz County

Dear Supervisors:

There is considerable controversy as well as differences of professional and scientific opinion on the issue of Genetically Modified Organisms in agriculture.

I have been involved in sustainable agriculture for over 25 years, and many of the farmers and researchers in this movement have developed sustainable farming systems that do not involve the co-dependency on pesticides and herbicides that current GMO farmed crops do. GMO's are legally prohibited for use in organic farming and are an extension of the herbicide/pesticide dependent model of industrial agriculture. The critical difference, however, is that we have developed mechanisms to keep toxic pesticides and herbicides off of organic crops and out of our food. With GMOs, the scientific consensus is that contamination is inevitable - those genes cannot be kept out. There is no protection for organic or any other non-GMO crops. That means that our choice to farm and eat without biotech pollution is being taken away.

The biotech industry has failed to fully inform the public of the entire picture: why is there no mention of the risks associated with using GMO crops, risks such as increased weed resistance, leading to documented higher use of more toxic herbicides; risks such as economic ones, as in the case of loss of markets for hundreds of farmers over thousands of acres in western Canada with organic canola contaminated by GMO canola; issues such as the high cost of the seed and the inability of farmers to conduct traditional seed-saving, the absence of liability protection for farmers whose markets are ruined by GMO contamination, and the inadequacy of testing for human food consumption.

There may be promise in the future for GMO's in agriculture, but currently the benefits to

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farmers, to the public and to the environment of the billions of dollars in research are scant, to say the least. Some of those billions might be better spent for research on true sustainable agricultural systems that focus on pesticide-use reduction and increasing biodiversity on farms. Biotech proponents claim that GMO's have led to reduced pesticide use, but the facts don't support that claim.

At this point, the risks in terms of genetic pollution, loss of markets and absence of liability seem to argue in favor of taking the cautious route, and instituting a moratorium that can be lifted when these major concerns are addressed.

Sincerely,

Sam Earnshaw

CBD BOSMAIL

m: CBD BOSMAIL
Sent: Monday, June 05,2006 6:03 PM
To: CBD BOSMAIL
Subject: Agenda Comments

Meeting Date : 6/6/2006

Item Number : 58

Name : Thomas Wittman

Email : twittman@cruzio.com

Address : 8315 Hermosa Ave
Ben Lomond, CA 95005

Phone : 831-336-2852

Comments :
Dear Supervisors,

I am a member of Molino Creek Farming Collective, an organic farm in Santa Cruz County, for twelve years I held the position of President of the Central Coast Chapter of the California Certified Organic Farmers, and am a current member of the Board of the Ecological Farming Association. I urge the Supervisors to accept the recommendations of the GMO subcommittee.

For the last ten years I have been editing a daily email news service about genetically engineered crops. I have read many thousands of news reports from around the world about contamination of GE crops, of health problems related to GE crops in laboratory animals, domestic livestock, and in human populations where they are subject to exposure to fields of **GE** crops.

One thing I have also learned is that this technology is in no way under control. Contamination to other crops is inevitable. Containment of pollen of any field crop is impossible. Even containment in an enclosed space is subject to pollen escaping in many ways. One grain of pollen escaping into the open air can potentially contaminate crops it is compatible with for centuries or forever. There is no putting this genie back in the bottle. Imagine if a person brought one seed from a corn plant grown in the US heartland for ethanol and planted it near an organic sweet corn field in Santa Cruz County. Contamination is almost certain. Without knowledge of this activity or laws to prevent it, soon our organic crops would be contaminated. Our choice for non GE foods would be gone.

Scientists do not even know how to test for health related problems yet as this technology is so new and the organisms produced are completely new to our earth. Please do not be deceived into thinking this is not a new process and is similar to conventional breeding. In a natural system, species barriers can never be crossed. The potential for food allergies, side effects of plants that are pesticides, and unknown disruption of our digestive processes is unknown. Animals must be fooled into eating it. Dr John Hagelin, a year 2000 United States Presidential candidate and the familiar scientist in the popular "What the Bleep Do We Know" movie says, "We need mandatory labeling and safety testing of genetically engineered foods, plus a moratorium on the release of these experimental life forms into the environment until proven safe. It is essential that the American people act without delay to preserve their own health and that of future generations."

The incredible high investment in making this technology, forcing unlike organisms into new ones, has

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caused an unprecedented rush to the marketplace trying to keep investors happy. Along with the danger of rushing into this is the impact these technologies on our ability to provide a local food system. Is our food system local when we can only buy seed from multinational corporations and saving seed is illegal?

The question at hand is choice. Here we are in the Mecca of organic farming, in an environment of progressive thinkers. Many of you feed your children and yourselves from the wonderful bounty of organic produce we produce here. Often this choice is health related. But with GE crops contaminating our organic crops that choice will disappear. The wisdom and hope of buying organic foods will disappear into uncertainty.

I strongly believe that much more time is needed before we can let our world class food system be contaminated by an industrial crop that may not even be grown for food. I think we need to show that we are concerned and delay going on this one way path until it is proven safe.

Respectfully,

Thomas Wittman

CBD BOSMAIL

›m: CBD BOSMAIL
Sent: Monday, June 05,2006 4:24 PM
To: CBD BOSMAIL
Subject: Agenda Comments

Meeting Date : 6/6/2006

Item Number : 58

Name : Stacie Clary

Email : sclary7@yahoo.com

Address : 706 Gilroy Dr.
Capitola CA 95010

Phone : Not Supplied

Comments :
I am writing to urge your support of the Precautionary Moratorium on GE crops in the county, as your subcommittee recommends. GMOs have not been adequately tested for impacts to both human and environmental health. There are no regulations protecting our county's organic farmers from contamination. As long as the state and federal governments do not provide protection from GE crops, it is imperative that the county do so.

‹nk you for your time.

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CBD BOSMAIL

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m: CBD BOSMAIL
Sent: Monday, June 05, 2006 4:46 PM
To: CBD BOSMAIL
Subject: Agenda Comments

Meeting Date : 6/6/2006

Item Number : 58

Name : Deborah Yashar

Email : debbyry@hotmail.com

Address :

Phone : Not Supplied

Comments :
I am writing to express my support of the Precautionary Moratorium and the findings of the **GE** Subcommittee. As a professional with a B.A. in sustainable agriculture who works and represents small-scale organic growers in Santa Cruz and Monterey County, I am especially concerned about GE liability issues. Currently, no Federal or State laws protect organic or non-GE conventional growers from GE drift or the subsequent financial harm and market loss. GE contaminated growers are forced to bear all of the costs associated with pursuing a private lawsuit against the multi-national GE polluter. The migration of GE organisms beyond the designated farm is inevitable, and we should avoid this disastrous consequence from occurring in Santa Cruz County. I am also concerned about the threat of GEs to my own land of 33 acres in the Santa Cruz Mountains- an area identified to be inhabitated with rare and endangered species of flowering plants, trees and insects. Through cross-pollination GE crops are genetically contaminating weedy relatives, creating 'super weeds' that are resistant to one or more herbicides and prone to further spreading. I respectfully urge the Santa Cruz Board of Supervisors to support the passage of a Precautionary Moratorium in order to protect our local biodiversity and the organic farmers who steward it.
Sincerely,
Deborah Yashar

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CBD BOSMAIL

m: CBD BOSMAIL
Sent: Monday, June 05,2006 6:11 **PM**
To: CBD BOSMAIL
Subject: Agenda Comments

Meeting Date : 6/6/2006

Item Number : 58

Name : Mark Lipson

Email : mark@ofrf.org

Address : Organic Farming Research Foundation
303 Potrero St., Suite 29-203, Santa Cruz 95061

Phone : 831-426-6606

Comments :
6/5/06
TO: Santa Cruz County Board of Supervisors
RE: Report and Recommendations of the "GE Subcommittee of the Public Health Commission"

I write to urge the Board's adoption of the full report and recommendations from the Public Health C nmission's "GE Subcommittee." The proposed "Precautionary Moratorium" and the conditions described ı ,emoving such a moratorium are thoroughly researched, well balanced, and should be implemented. Further, they provide a model for public policy regarding these issues that should be widely adopted by other governmental bodies.

As the national Policy Program Director of the Organic Farming Research Foundation, I have studied the scientific and policy aspects of transgenic organisms in agriculture for nearly 10 years. From 199-2001 I served on the USDA's Advisory Committee for Agricultural Biotechnology (ACAB) by appointment from the Secretary of Agriculture.

In representing organic producers on ACAB and in other stakeholder processes concerning transgenic crops, I have observed great polarization and contention within the agricultural community, and between agriculture and other interests. The proposals made by the GE Subcommittee are unique in finding relatively common ground, and making common sense for a wide variety of producers and agricultural processors, as well as consumers and public interest advocates.

Thank you for chartering the Committee and giving its proposals full and careful consideration.

Sincerely,
Mark Lipson
Policy Program Director
Organic Farming Research Foundation
www.ofrf.org
' '-426-6606

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CBD BOSMAIL

m: CBD BOSMAIL
Sent: Monday, June 05,2006 11:28 PM
To: CBD BOSMAIL
Subject: Agenda Comments

Meeting Date : 6/6/2006

Item Number : 58

Name : Angela Flynn

Email : angelaflynn80@msn.com

Address : 246 Moore Street
Santa Cruz, CA 95060

Phone : 831-469-4399

Comments :
Dear Board of Supervisors,

I have come to this meeting today to address a topic that I feel is of the utmost importance for Santa Cruz, California, our country and the world. This is genetic engineering. As an organic farmer, gardener and consumer and as someone who has been following the development of this field for the last decade I have come to have great concern over the laissez faire attitude that the US government has taken in regulating genetically engineered crops and animals.

Our government tells us that genetically engineered foods are substantially equivalent to non-genetically engineered foods. Common sense alone dictates that if a foreign gene is inserted into a gene the result is not equivalent to the original gene. Experience has shown this to be true as new allergens and proteins have been discovered in genetically engineered foods. Carcinogenic, mutagenic and poisonous substances have been indicated as well. The US Food and Drug Administration allows the biotech industry to conduct it's own testing with no oversight. One of the major biotech multi national companies, Monsanto, happens to be the same multi national that brought the world pcbs and agent orange. Allowing a company with a track record of deceiving the public on the dangers of it's products to self police itself and then to trust their published results is either total stupidity or complicit deception by the FDA.
Genetically engineered crops cross-pollinate with non-genetically engineered crops. This destroys the rights of farmers to grow crops that are free from genetic contamination. It destroys the livelihood of organic farmers. The US Judicial System has consistently sided with the biotech industry by ruling that ge contamination in a farmer's fields means that the farmer has to pay royalties to the patent holder of the ge crop. This goes beyond stupidity and deception. We now cross over to the absurd.
As the biotech industry tries to force feed the world with its product, people all over the world have refused to buy the assurances that genetically engineered foods are inherently safe. I was encouraged last year when this Board of Supervisors formed a Task Force to investigate the issue. I have managed to make it to some of the Task Force's meetings and have been greatly impressed by the thorough research they conducted. I am in complete agreement with the recommendation of a Precautionary Moratorium.
A precautionary moratorium places the responsibility back onto the biotech industry. It does not say that genetic engineering is necessarily wrong or unsafe, only that there needs to be more adequate controls to ensure the health and environmental concerns associated with this new technology. California is the role model in the United States on health and environmental regulation. By enacting this Precautionary Moratorium this Board of Supervisors will continue this legacy. Thank you.

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CBD BOSMAIL

om: CBD BOSMAIL
Sent: Tuesday, June 06,2006 6:53 **AM**
To: CBD BOSMAIL
Subject: Agenda Comments

Meeting Date : 6/6/2006

Item Number : 58

Name : Patricia Carney

Email : healthystem@yahoo.com

Address : 471 Sims Road
Santa Cruz, CA 95060

Phone : 831-423-0991

Comments :
I urge you to please support of the Precautionary Moratorium and the findings of the GE Subcommittee.

I have been proud to say I feel blessed to live in Santa Cruz because of the abundance of organic food grown here and available to us year-round. 90% of the food I eat is organic.

We don't know the real long-lasting effects of GMO. Please don't let Santa Cruz be one of the testing grounds. Keep our organic foods safe and pure.

Respectfully,
Patricia Carney

CBD BOSMAIL

From: CBD **BOSMAIL**
Sent: Monday, June 05,2006 4:02 PM
To: CBD BOSMAIL
Subject: Agenda Comments

Meeting Date : 6/6/2006

Item Number : 58

Name : Susan Agbelekale

Email : Not Supplied

Address : Not Supplied

Phone : Not Supplied

Comments :
I am particularly concerned about health and environmental risks of genetically engineered crops. I believe this is another area where technology is moving faster than our developing knowledge about the short and long term effects of altering our food and environment. Please do your part to help protect the land and citizens Santa Cruz by adopting this Precautionary Moratorium on the growing of GE crops until some commons sense measures are established.

Thank you.

CBD BOSMAIL

n: CBD BOSMAIL
Sent: Tuesday, June 06,2006 7:26 AM
To: CBD BOSMAIL
Subject: Agenda Comments

Meeting Date : 6/6/2006

Item Number : 58

Name : Lisa J. Bunin

Email : bunin@cruzio.com

Address : PO Box 2306
Santa Cruz, CA 95063

Phone : 425-7121

Comments :
Statement to Santa Cruz County Board of Supervisors:

Adopt a Precautionary Moratorium on the Growing of Genetically Engineered Crops

6 ne 2006

Good-morning.

My name is Lisa Bunin. I am a member of the Genetic Engineering Subcommittee of the Public Health Commission. I have a Ph.D. in Environmental Sociology and I work as an Environmental Policy Consultant on sustainable agriculture issues.

I want to thank Supervisors Pirie, Warmhoudt, and Stone for creating this important Subcommittee to study the potential impacts of growing genetic engineered crops in our county.

In the few minutes I have, I would like to tell you a story about research that I conducted on behalf of the GE Subcommittee.

One of the charges of our Subcommittee was to investigate the status of GE test crops in our County. After discovering that neither the Agricultural Commissioner nor the California Department of Food and Agriculture had such records, we agreed that I should file a Freedom of information request with the USDA.

I filed seven Freedom of Information requests to obtain information on the crops grown in Santa Cruz and the surrounding counties, because pollen and seeds do not respect county lines. My request included a list of 14 questions aimed at securing basic information such as the name of companies conducting field tests, GE traits being tested, the location and acreage of field tests, field test results, and any violations, citations ε reprimands issued by the USDA, among other things.

I think that people living in our county have the right to know where GE crops are grown and if they are living near GE test farms. Access to such information should be made easily available to anyone who wants it. Yet, I was unable to obtain this information. More than six months have passed, and six of my seven

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Freedom of Information requests remain unanswered. In fact, I only received one substantive response which stated that the USDA was "unable to locate any records responsive to [my] request" about GE test crops grown in Santa Cruz County between 2004 and 2005.

Yet, even this information may not be entirely accurate. The USDA's own Inspector General has cast doubt upon the Agency's ability to oversee GE field tests and to track, monitor, and evaluate test results. In a report released in December 2005, the Inspector General criticized the USDA for not effectively monitoring required field test information, including any harmful effects on the environment that may have resulted from such field tests.

My research showed the Subcommittee that no reliable regulatory infrastructure exists at the federal, state or county level to provide answers to basic questions about GE field test, or to protect public health and the environment.

As a Santa Cruz County resident, I treasure the convenient access I have to fresh, diverse, locally-grown, nutritious, and tasty organic fruits and vegetables. I know that I can eat locally grown, healthy, organic food year round and buy it at one of the seven farmers' markets in the county.

By passing a Precautionary Moratorium on the growing of GE crops, the Board will ensure that people living in our vibrant coastal community will continue to have access to non-GE contaminated food, if they want it. It will also ensure that the organic farming that our county is famous for will continue to grow and prosper.

I urge you to take precautionary action and to adopt a Precautionary Moratorium on the growing of GE crops in Santa Cruz County.

Thank you.

CBD BOSMAIL

n: CBD BOSMAIL
Sent: Monday, June 05,2006 5:57 PM
To: CBD BOSMAIL
Subject: Agenda Comments

Meeting Date : 6/6/2006

Item Number : 58

Name : Kristin Rosenow - Ecological Farming Association

Email : kristin@eco-farm.org

Address : 406 Main St., Suite 313
Watsonville, CA 95076

Phone : 831-763-2111

Comments :
Dear Santa Cruz County Board of Supervisors,
The Ecological Farming Association is a 26 year-old Watsonville-based non-profit that is dedicated to educating farmers, policy makers and the public about practical and economically-viabletechniques of ecological agriculture. EFA supports a vision for our food system where strengthening soils, protecting air and water, and encouraging diverse ecosystems and economies are all part of producing healthful food. (innovative programs bring together growers, consumers, educators, activists, and industry related businesses to exchange the latest advances in sustainable food production and marketing.
The Ecological Farming Association fully supports the GE Subcommittee recommendation of a Precautionary Moratorium on the growing of GE crops in Santa Cruz County until the recommended measures are established to ensure the protection of public health, the environment and our agricultural economy.

We believe that Genetic Engineering of food crops is the ultimate example of how out-of-control our food production system has become and that it is now more responsive to corporate bottom lines than to the long-term health of our children and communities. We are at a crossroads in terms of the food production legacy that we will leave behind for our children and grandchildren. Will we leave behind a toxic-chemical dependent food system reliant on multi-national corporations for permission to plant patented seeds containing genes from who knows what other species? Will we leave them with illnesses and allergies and an irretrievably contaminated environment because we failed to thoroughly study the consequences of our new technologies on human health and the environment?

The decisions that we make now about genetic engineering in food crops will have permanent consequences on our food production capacity. The Ecological Farming Association believes that such an important decision should be subject to fully informed public debate. We applaud the formation of the GE Subcommittee and the due diligence of its investigation. Our exploration of this issue has yielded many of the same conclusions: inadequate regulation at the state and federal level, regulation that is rife with conflicts of interest, lack of human health testing, and no protection for farmers and consumers that would c' ose not to participate in this genetic experiment. These are only a few of the reasons for Santa Cruz (nty to approach this technology with precaution. The Ecological Farming Association has invested considerable resources in investigating and debating this issue and we believe that the measures recommended by the GE Subcommittee are prudent and in the best interest of our community.

Thank you for your consideration.

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6/6/2006

Sincerely,

Kristin Rosenow
Executive Director

CBD BOSMAIL

From: CBD BOSMAIL
Sent: Monday, June 05,2006 5:27 PM
To: CBD BOSMAIL
Subject: Agenda Comments

Meeting Date : 6/6/2006

Item Number : 58

Name : Arty Mangan

Email : amangan@got.net

Address : 12333 Irwin Way
Boulder Creek

Phone : 831-338-1202

Comments :
Dear SC Board of Supervisors,

I served on the Santa Cruz GE Subcommittee. I've worked in food and agriculture related industries since 1978. For 12 years I was the head fruit and vegetable buyer for Odwalla buying directly from farmers and p- -king-houses and presently I am presently involved in sustainable agriculture work.

I want to thank Supervisor Pirie and the rest of the Board of Supervisors for acknowledging the seriousness of the issue by calling the genetic engineering subcommittee together and I want to thank Mark Stone for giving me the opportunity to serve on it.

The members of the subcommittee are a diverse group with different opinions representing conventional and organic agriculture, county health services, the public health commission and concerned citizens.

The sub-committee did 10 months of extensive research as is represented and cited in the report. Based on the thorough vetting of that research, the subcommittee came to the conclusions and recommendations of the report before the board, which I urge the Board will support.

Despite differing opinions the GE Subcommittee worked extremely hard at creating a consensus on all the key criteria in which it feels genetic engineered crops could be grown and at the same time provide the necessary precautions to preserve public and environmental safety.

It was no accident that that the Board of Supervisors convened this committee under the auspices of the Public Heath commission, because although the agricultural aspects of genetic engineering are significant, the issue has a much greater scope that agriculture alone.

Its scope includes fair choice for consumers in what they eat, choice for farmers in what they grow and the protection of Santa Cruz's unique environment and the health of its citizens.

. . subcommittee is fully aware that the regulatory responsibility for the mentioned safeguards should be the responsibility of the federal and state regulatory agencies.
The subcommittee found that the federal regulations are not only inadequate at best but, as proven by a USDA audit of its own protocols, they are not living up to their own insufficient standards.

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The state of California has no real regulatory structure in place for GE and is not even empowered to know where trail plantings of things like pharmaceutical drugs grown in crops are located.

The fact that the federal and state regulatory agencies are in default of their responsibility to protect the public interest, forces us at the county level to put in place common sense measures that will safeguard our citizens.

Long term human health testing or assessments have not been done on GE foods prior to approval. Subsequent health studies have shown that genes inserted into genetically engineered food not only survive digestion, but transfer into body organs and circulation. DNA can even travel via the placenta into the unborn.

GE foods create a potential risk for allergies, toxicity, carcinogens, altered fertility, increased antibiotic resistance, novel infectious diseases, and can have adverse impacts on the human immune system, and metabolism.

Since no government agency monitors human health impacts of GE foods, claims made about their safety have no real basis.

So, I urge you to please adopt all the common sense recommendations in the subcommittee report.

Sincerely,

Arty Mangan

CBD BOSMAIL

From: CBD BOSMAIL
Sent: Tuesday, June 06, 2006 7:59 AM
To: CBD BOSMAIL
Subject: Agenda Comments

Meeting Date : 6/6/2006

Item Number : 58

Name : Debra L. Klein

Email : dklein@gavilan.edu

Address : 2076 Chanticleer Ave.
Santa Cruz, CA 95062

Phone : 831-462-2276

Comments :
Debra L. Klein
June 6, 2006

RE: PLEASE SUPPORT THE PRECAUTIONARY MORATORIUM ON THE GROWING OF GE CROPS

As a Community College Instructor, Professor of Anthropology, and resident of Santa Cruz, I am shocked that there is currently NO infrastructure in place to regulate the growing of GE foods in Santa Cruz County! One of the primary reasons I have chosen to make Santa Cruz my home is because of this county's environmentally conscious and politically progressive communities. I am one of the 76% of Santa Cruz residents who buys organic foods on a regular basis (See: www.sccfb.com). The looming prospect of unregulated GE foods being sold in our grocery stores and farmers' markets is horrifying to me, my family, and friends!

in the courses that I teach at Gavilan College, my students and I have recently researched the social and health implications of genetic engineering with regard to our food sources. In concurrence with the findings of the GE subcommittee, we have found that:
. No long-term human health testing or assessments have been done on GE foods.
. GE foods create a potential risk for allergies, toxicity, carcinogens, altered fertility, increased antibiotic resistance, infectious diseases, and adverse impacts on the human immune and endocrine systems.
. Since no government agency monitors human health impacts, no claims can be made about the safety of GE.
In the United States in 2006, my students and I have come to the conclusion that US citizens do not have easy access to information so that we can make the most informed choices on local, state, and national levels. For example, pesticide and agribusiness industries are driven by profit over concern for people's health and safety. This is not the case in many European nations, Canada, and even some African nations. My hope is that Santa Cruz county, however, will adopt a Precautionary Moratorium on the growing of GE crops until measures are established to ensure the protection of public health, the environment, and Santa Cruz's agricultural economy.

I am personally very grateful for the efforts and vision of the GE Subcommittee and can only hope that the County Board of Supervisors understands the seriousness and timeliness of this issue.

Sincerely,

6/6/2006

Debra L. Klein, Ph.D.
Anthropology Instructor
dklein@gavilan.edu
831-462-2276

LIST OF CALLERS REGARDING ITEM 58

Name: Valerie Lasciak
1555 Merrill Street, #139
Santa Cruz, CA 95062

Comment: Concerned about growing genetically engineered food crops outdoors. Afraid they will contaminate other crops.

Name: Jim Nelson
Camp Joy Farm
131 Camp Joy Road
Boulder Creek, CA 95006

Comment: Follow Genetically Engineered subcommittee's recommendation to pass a precautionary moratorium on GE crops.

Name: Jay Nitiaman
230 Forest Avenue
Santa Cruz, CA 95062

Comment: All food that I eat is organically grown locally. I hope you will vote for a moratorium.

Name: Staci Clary
706 Gilroy Drive
Capitola, CA 95010

Comment: In support of moratorium as recommended by committee.

3732C6

#58

APPENDIX 6: Santa Cruz County Code, Title 7, Health and Safety, Chapter 7.31 Genetically Engineered Crop Moratorium

Santa Cruz County GMO Moratorium Ordinance

http://municipalcodes.lexisnexis.com/codes/santacruzco/_DATA/TITLE07/Chapter_7_31_GENETICALLY_ENGINEERE/index.html

Title 7 HEALTH AND SAFETY

Chapter 7.31 GENETICALLY ENGINEERED CROP MORATORIUM

7.31.010 Findings.

7.31.020 Definitions.

7.31.030 Prohibition.

7.31.040 Exemptions.

7.31.050 Reevaluation by board of supervisors.

7.31.060 Enforcement.

7.31.070 Severability.

7.31.010 Findings.

A. There is inadequate regulatory monitoring and oversight of genetically engineered crops by the federal and state government necessary to ensure public health and environmental safety. The planting of genetically engineered crops is not required to be publicly disclosed to any federal, state or county agency.
B. Health testing of the effects of exposure to genetically engineered organisms in food 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 genetically engineered foods.
C. Farmers and gardeners who choose not to grow genetically engineered crops currently have no clear legal recourse if their nongenetically engineered crops are contaminated by genetically engineered pollen or seeds.
D. There is currently no legal requirement to label genetically engineered seeds or rootstock, thus limiting farmers' or gardeners' choices.
E. Currently, adequate safeguards do not exist to prevent genetically engineered contamination of nongenetically engineered crops, plants, insects, domesticated animals, wildlife and wildlands, that can result from forces of nature and human causes. The resulting impacts on ecosystems are unknown. (Ord. 4830 § 1 (part), 8/1/06)

7.31.020 Definitions.

For the purposes of this chapter, unless the context otherwise indicates, certain words and phrases used in this chapter are defined as follows:
"Genetic engineering" means a process or technology employed whereby the hereditary apparatus of a living cell is altered, modified or changed so that the cell can produce more or different chemicals or perform completely new functions.
"Genetically engineered crop" means a crop that has been created or modified through genetic engineering. It does not include nonliving or nonreproducing organisms or products.
"Person" means any individual, firm, partnership, trust, corporation, company, estate, public or private institution, association, organization or group, and any representative, officer, employee or agent of any of the foregoing.
"Release" means to discharge, emit or liberate any genetically engineered organism, or the product of a genetically engineered organism into the open environment. (Ord. 4830 § 1 (part), 8/1/06)

7.31.030 Prohibition.

It is unlawful for any person to propagate, cultivate, raise, or grow any genetically engineered crop. Any act in violation of this prohibition is declared to constitute a public nuisance. (Ord. 4830 § 1 (part), 8/1/06)

7.31.040 Exemptions.

The prohibition contained in this chapter shall not apply to the planting or production of genetically engineered pharmaceuticals and industrial compounds 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. (Ord. 4830 § 1 (part), 8/1/06)

7.31.050 Reevaluation by board of supervisors.

In its discretion, the board of supervisors may consider the on-going need for the prohibition on genetically engineered food crops contained in Section 7.31.030 of this chapter. If the board of supervisors determines that the prohibition is no longer necessary it shall amend this chapter in a manner consistent with that determination. The board of supervisors may consider, including but not limited to, the following factors:
A. If the state of California and/or the federal government has implemented and effectively enforced its own regulatory system that regulates genetically engineered crops.
B. If field trials of genetically engineered crops are required to be contained to prevent contamination of organic and nongenetically engineered crops and weedy relatives.
C. If 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.
D. If genetically engineered seeds and root-stock shall be required to be labeled so that farmers and gardeners can choose whether or not they want to grow genetically engineered crops.
E. If the types and location of the genetically engineered crops currently being grown and tested in Santa Cruz County shall be communicated to the agricultural commissioner and available to the public upon request. (Ord. 4830 § 1 (part), 8/1/06)

7.31.060 Enforcement.

A. It shall be the duty of the agricultural commissioner to enforce this chapter, and all designated officers of the agricultural commissioner are charged with the enforcement of this chapter and each and every provision thereof.
B. Any person, whether as principal or agent, employee or otherwise, who knowingly violates or causes or permits the violation of any of the provisions of this chapter, shall be guilty of a misdemeanor, and upon conviction thereof, shall be punishable by a fine of not more than one thousand dollars or by imprisonment in the county jail of the county of a term not exceeding six months or by both such fine and imprisonment. Such person shall be deemed to be guilty of a separate offense for each day during any portion of which any violation of this chapter is committed, continued or permitted by such person and shall be punishable as herein provided.
C. Any use of the land, building or premises, established, conducted, operated or maintained contrary to the provisions of this chapter, shall be, and the same is declared to be a violation of this chapter and a public nuisance.
D. The county may summarily abate, or abate pursuant to Chapter 1.14 of this code, any public nuisance and the county counsel or the district attorney, upon order of the board of supervisors, may bring civil suit, or other action, to enjoin or abate the nuisance.
E. Each day any violation of this chapter continues shall be regarded as a new and separate offense. The remedies provided in this chapter shall be cumulative and not exclusive.
F. Any person who creates or maintains a public nuisance in violation of this chapter shall be liable for the costs of abatement that shall include, but not be limited to:
1. Costs of investigation;
2. Costs of removing genetically engineered crops from the open environment, cleanup and restoration of the environment;
3. Cost of county employee enforcement time;
4. Court costs; and
5. Costs of monitoring compliance.
G. Should an enforcement action be filed by the county pursuant to this chapter, no action shall be taken on any application relating to the property upon which the genetically engineered crops were located until the violation has been resolved. (Ord. 4830 § 1 (part), 8/1/06)

7.31.070 Severability.

The provisions of this chapter are severable. If any section, paragraph, sentence, phrase or word of this chapter is declared invalid for any reason, that decision shall not affect any other portion of this chapter, which shall remain in full force and effect. (Ord. 4830 § 1 (part), 8/1/06)

APPENDIX 7: GE Subcommittee: Minority Report on Response to Board of Supervisors

0000483

MINORITY LETTER - ATTACHMENT C

GE SUBCOMMITTEE

MINORITY REPORT ON RESPONSE TO BOARD OF SUPERVISORS

We are Subcommittee members who disagree with the majority regarding the presentation to your Board of a proposed precautionary moratorium on the planting and production of GE crops in Santa Cruz County, to the exclusion of any other alternatives

After many months of meetings including hours of discussions on the merits of the collected research data, it is clear to us that there are other options that should be presented to the Board for consideration.

Recognizing that science has been dynamic and innovative in keeping the agricultural industry competitive and profitable we do not believe there is supporting evidence to justify intervention at the local level.

The minority believes this technology holds promise, and we do not want to close the door on those opportunities for increased yields, reduced pesticide use and reduced tillage, which results in cleaner water and air through reduced emissions and soil erosion. If the Board of Supervisors wishes to impose heavier restrictions on biotech crops, we ask the Board to allow protections for those that could potentially benefit from this technology, by implementing reasonable, achievable access to biotech crops.

Although there is GE research being conducted on various crops that are also grown in Santa Cruz County, there are no biotech crops on the marketplace that would immediately impact our farming community. In California, most biotech crop production to date has been limited to only three crops: cotton, corn and alfalfa. Most biotech research is not financially conducive for fruits and vegetables therefore any potential production in biotech specialty crops is unlikely to impact the immediate future of Santa Cruz County.

We believe the Board of Supervisors should have more than one option in deciding this important issue. Therefore, we offer the following options for the Board's consideration:

1) Take no action: There is no known interest by production agriculture to plant GE crops in Santa Cruz County at this time.

2) Request that legislators seek funding at the state and national level to provide for enforcement of existing regulations. This could be by Resolution of the Board.

3. Table the issue for the time being until more information is available, as this is an emerging industry that is not currently threatening the health or safety of the citizens of Santa Cruz County.

4. Create a biotech crop "clearing house" with the Agricultural Commissioner's office. If GE crops are grown in Santa Cruz County, the type and location of GE crops grown and tested in Santa Cruz County shall be communicated to the Agricultural Commissioner prior to planting, and the information made available to the public upon request. This would allow for any potentially affected growers to make adjustments and/or agreements with their neighbors when making planting decisions.

0000484

MINORITY LETTER - ATTACHMENT C

5. Amend Chapter 7.30 of the Santa Cruz County Code, to include the suggested language of the subcommittee's precautionary moratorium. This law has been in effect since 1988.

- Field trials of genetically engineered crops are contained to prevent contamination of organic and non-GE crops and weedy relatives.
- 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 ,
- 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.
- GE seeds and root-stock shall be labeled so that farmers and gardeners can choose whether or not they want to grow GE crops.
- 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.

In summary, we feel that there should be more than one option available to the Board in making their decision on how to address the GE issue as it pertains to Santa Cruz County.

APPENDIX 8: Santa Cruz County Code, Title 7, Health and Safety, Chapter 7.30, "Noticing Requirements, Indemnification and Financial Assurances for the use of Recombinant DNA technology"

Chapter 7.30
NOTICING REQUIREMENTS, INDEMNIFICATION AND FINANCIAL ASSURANCES FOR THE USE OF RECOMBINANT DNA TECHNOLOGY

Sections:

7.30.010 Findings.
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7.30.010 Findings.

A. Uses of recombinant DNA processes involving the release of genetically engineered organisms into the open environment may pose risks to public health, safety and the environment not adequately addressed under current federal and state regulations.

B. While the control of the release of genetically engineered organisms into the environment may generally be considered the responsibility of federal and state governments, it is local government that may initially be called upon to respond to any adverse effects on public health, safety and the environment, resulting from the release of such organisms into the open environment.

C. In order for local government to have the capacity to provide appropriate response in such instances, it is, at minimum, necessary for local government to have notice of all uses of recombinant DNA technology and the genetically engineered organisms created by the recombinant DNA process which have not been approved by either the state or federal government for use in the manner and for the purposes now proposed.

D. In order to protect the public health, safety and the environment, it is in the public interest for local government to establish rules and requirements for such activity involving recombinant DNA technology. (Ord. 3904 § 1 (part), 1988)

7.30.020 Purpose.

The purpose of this chapter is to establish policy, standards and requirements pertaining to the use of recombinant DNA technology so that public health and safety and the environment be afforded the maximum degree of protection. It is not the intent of this chapter to enter the regulatory sphere occupied by federal and/or California State Government; rather, it is the intent of this chapter to more fully carry out the county's health and safety authority in areas not presently covered by state or federal law or regulation. (Ord. 3904 § 1 (part), 1988)

7.30.030 Applicability.
This chapter is applicable to the use of recombinant DNA technology, the use of genetically engineered organisms created by the recombinant DNA process, or the use of any product created thereby, within the unincorporated portions of the county of Santa Cruz subject to the following exceptions:

A. Any use of any "economic poison" as defined in Section 11501.1 of the California Food and Agricultural Code, and certified by the California Department of Food and Agriculture for its use, experimental or otherwise, in the manner and for the purposes now proposed.

B. Any use of recombinant DNA technology, genetically engineered organisms created by the rDNA process, or products created thereby, duly given final approval and certified by the federal and/or California State Government for its use (experimental or otherwise) in the manner and for the purposes now proposed. (Ord. 3904 § 1 (part), 1988)

7.30.040 Definitions.
For the purposes of this chapter, unless the context otherwise indicates, certain words and phrases used in this chapter are defined as follows:

A. "DNA" means deoxyribonucleic acid.

B. "Genetically engineered organisms" means organisms including bacteria, fungi, protozoa and viruses, created or modified by recombinant (rDNA) technology. It does not include nonliving or nonreproducing organisms or products.

C. "Genetic engineering" means a process or technology employed whereby the hereditary apparatus of a living cell is altered, modified or changed so that the cell can produce more or different chemicals or perform completely new functions.

D. "Open environment" means an area outside a particular sealed environment in which the subject rDNA material is contained.

E. "Person" means any individual, firm, partnership, trust, corporation, company, estate, public or private institution, association, organization or group, and any representative, officer, employee or agent of any of the foregoing.

F. "Recombinant DNA (rDNA)" means molecules that:

1. Consist of different segments of deoxyribonucleic acid (natural or synthetic) that have been joined together in an environment outside any cell or cellular organisms and which have the capacity to replicate in some host cell either autonomously or after they have been integrated into the host cell's geonome; or

2. Are the result of a replication of the DNA molecules described in subsection F1 of this section.

G. "Use of recombinant DNA technology" or "DNA technology" means an activity, either commercial or noncommercial, undertaken by any person to use recombinant

DNA for any purpose, including but not limited to the creation of a product or by-product of genetically engineered organisms, when that use involves the entrance of recombinant DNA into the host cell or the packaging of such DNA into a vector capable of effecting such an entrance.

H. "Release" means to discharge, emit or liberate any genetically engineered organism, or the product of a genetically engineered organism, created by the recombinant DNA process into the open environment. (Ord. 3904 § 1 (part), 1988)

7.30.050 Notice.

A. No person shall make nonexempt use of rDNA technology within the unincorporated portions of the county of Santa Cruz, without first providing notice at least ninety days in advance of such activity to both the county health officer and the clerk of the board of supervisors of the county of Santa Cruz.

B. The required notice shall include the following information:

1. The name, mailing and office address, telephone number and authority of the person submitting the notice.

2. A complete description of the proposed rDNA technology activity. (Ord. 3904 § 1 (part), 1988)

7.30.060 Indemnification and financial assurances.

A. The person proposing each and every nonexempt use of rDNA technology shall indemnify and hold harmless the county and its officers, agents and employees from actions or claims of any description brought on account of any injury or damages sustained (including death) by any person or property resulting from the proposed rDNA activity.

B. The person proposing each and every nonexempt use of rDNA technology shall provide financial assurances that are adequate to respond to damage claims arising from such use. Such financial assurances shall be in the form of a trust fund, surety bond, letter of credit, insurance or other equivalent financial arrangement in a form determined to be satisfactory by the county, and shall be in an amount determined to be satisfactory by the county. (Ord. 3904 § 1 (part), 1988)

7.30.070 Enforcement.

A. It shall be the duty of the health officer of the county of Santa Cruz to enforce this chapter, and all designated officers and employees of the county department are charged with the enforcement of this chapter and each and every provision thereof.

B. Any person, whether as principal or agent, employee or otherwise, violating or causing or permitting the violation of any of the provisions of this chapter, shall be guilty of a misdemeanor, and upon conviction thereof, shall be punishable by a fine of not more than one thousand dollars or by imprisonment in the county jail of the county of a term not exceeding six months or by both such fine and imprisonment. Such person, agency, firm or corporation shall be deemed to be guilty of a separate offense

for each day during any portion of which any violation of this chapter is committed, continued or permitted by such person and shall be punishable as herein provided.

C. Any building or structure set up, erected, constructed, altered, enlarged, converted, moved or maintained, contrary to the provisions of this chapter, and/or any use of the land, building or premises, established, conducted, operated or maintained contrary to the provisions of this chapter, shall be, and the same is declared to be a violation of this chapter and a public nuisance.

D. The county may summarily abate, or abate pursuant to Chapter 1.14 of this code, any public nuisance and the county counsel or the district attorney, upon order of the board of supervisors, may bring civil suit, or other action, to enjoin or abate the nuisance.

E. Each day any violation of this chapter continues shall be regarded as a new and separate offense. The remedies provided in this chapter shall be cumulative and not exclusive.

F. Any person who creates or maintains a public nuisance in violation of this chapter shall be liable for the costs of abatement which shall include, but not be limited to:

1. Costs of investigation;

2. Costs of removing genetically engineered organisms from the open environment, cleanup and restoration of the environment;

3. Cost of county employee enforcement time;

4. Court costs;

5. Costs of monitoring compliance.

G. Should any person violate the terms of this chapter and any action be authorized by the board of supervisors, either by the county counsel, or the district attorney, or be in fact filed by either or both of such agencies for the violation, no other action shall be taken on any application filed by or on behalf of such person until the violation has been resolved, or such application is denied or conditionally approved. (Ord. 3904 § 1 (part), 1988)

7.30.080 Severability.

The provisions of this chapter are severable. If any section, paragraph, sentence, phrase or word of this chapter is declared invalid for any reason, that decision shall not affect any other portion of this chapter, which shall remain in full force and effect. (Ord. 3904 § 1 (part), 1988)

APPENDIX 9: Genetic Engineering in Lake County Agriculture, August 25, 2009

Genetic Engineering in Lake County Agriculture:

A Draft Report Submitted to the Board of Supervisors by the Genetically Engineered Crops Citizens' Advisory Committee

August 25, 2009

Committee Members

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Not every Committee member agrees with every viewpoint expressed. The Committee made a sincere effort to incorporate diverse points of view while maintaining accuracy to the best of its ability.

Chapter 1: Overview and Regulatory Framework

(Subcommittee One: Steve Devoto, Lorrie Gray, Marc Hooper, Liz Weiss)

a. United States Regulatory Agencies Unified Biotechnology Website (Hooper)
b. Food and Drug Administration (FDA) (Weiss)
c. Environmental Protection Agency (EPA) (Hooper)
d. United States Department of Agriculture (USDA) (All)
    i.. APHIS and Biotechnology Regulatory Services (BRS) (Hooper)
    ii. Government Accountability Office Review of Regulation of GE Crops (Devoto)
e. California Department of Food and Agriculture (CDFA) (Gray)
f. USDA National Organic Regulations (Devoto)

Part a. US Regulatory Agencies Unified Biotechnology Website

(http://usbiotechreg.nbii.gov) (Marc Hooper)

The Federal Government of the United States of America has a coordinated, risk-based system to ensure new biotechnology products are safe for the environment and human and animal health.

Established as a formal policy in 1986, the Coordinated Framework for Regulation of Biotechnology[1] describes the Federal system for evaluating products developed using modern biotechnology. (This is a 123 page document describing policy and procedures.)

The Coordinated Framework is based upon health and safety laws developed to address specific product classes.

The U.S. Government has written new regulations, policies and guidance to implement these laws for biotechnology as products developed.

This framework has allowed the United States to build upon agency experience with organisms and products developed using conventional techniques.

The website focuses on the agricultural products of modern biotechnology. At this time, the searchable database available on the site only covers genetically engineered crop plants intended for food or feed that have completed all recommended or required reviews for food, feed or planting use in the United States.

The U.S. Government agencies responsible for oversight of the products of agricultural modern biotechnology are the:

1. U.S. Department of Agriculture's Animal and Plant Health Inspection Service (USDA-APHIS),
2. U.S. Environmental Protection Agency (EPA),
3. Department of Health and Human Services' Food and Drug Administration (FDA)

Depending on its characteristics, a product may be subject to review by one or more of these agencies.

[1] http://usbiotechreg.nbii.gov/CoordinatedFrameworkForRegulationOfBiotechnology1986.pdf

Part b. Food and Drug Administration (FDA) (Liz Weiss)

The U.S. Regulatory Agencies Unified Biotechnology website states:

> The FDA is responsible for ensuring the safety and proper labeling of all plant- derived foods and feeds, including those developed through bioengineering. All foods and feeds, whether imported or domestic and whether derived from crops modified by conventional breeding techniques or by genetic engineering techniques, must meet the same rigorous safety standards. Under the Federal Food, Drug, and Cosmetic Act, it is the responsibility of food and feed manufactures to ensure that the products they market are safe and properly labeled. In addition, any food additive, including one introduced into food or feed by way of plant breeding, must receive FDA approval before marketing.

GAP: Consequently, if a food or feed manufacturer states their product is safe, the FDA assumes the manufacturer has done the proper testing. There is no government required long-term safety testing at this time. Industry is in charge of safety.

The FDA ensures that food and feed manufactures meet their obligations through its enforcement authority under the Federal Food, Drug, and Cosmetic Act. To help sponsors of foods and feeds derived from genetically engineered crops comply with their obligations, the FDA encourages them to participate in its voluntary consultation process. All foods and feeds from genetically engineered crops currently on the market in the U.S. have gone through this consultation process. With one exception, none of these foods and feeds were considered to contain a food additive, and so did not require approval prior to marketing.

GAP: At this time the Food Allergen Labeling and Consumer Protection Act of 2004 requires that food products that contain any ingredients containing protein derived from the eight major allergenic foods (peanuts, wheat, egg,.....) be labeled. In the U.S., no food labeling is required to identify genetically engineered products. [1]

GAP: March 27, 2009 the Department of Health and Human Services Inspector General noted that the government's system for tracing foods is full of potentially dangerous gaps. According to the report, 70 of 118 facilities failed to meet the FDA's record keeping requirements for information pertaining to suppliers, customers and shippers.

There have been several recalls in the past few months including the salmonella outbreak involving peanut products (nine deaths, nearly 700 ill) and a salmonella outbreak from Mexican jalapeno peppers initially blamed on tomatoes. [2]

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[1] http://usbiotechreg.nbii.gov/roles.asp
[2] http://www.injuryboard.com

Part c. Environmental Protection Agency (EPA) (Marc Hooper)

The EPA through a registration process regulates the sale, distribution and use of pesticides in order to protect health, and the environment, regardless of how the pesticide was made or its mode of action. This includes regulation of those pesticides that are produced by an organism through techniques of modern biotechnology.

The Biopesticides and Pollution Prevention Division of the Office of Pesticide Programs, under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), regulates the distribution, sale,

use and testing of pesticidal substances produced in plants and microbes. Generally, Experimental Use Permits are issued for field testing. Applicants must register pesticidal products prior to the sale and distribution, and the EPA may establish conditions for use as part of the registration. The EPA also sets tolerance limits for residues of pesticides on and in food and animal feed, or establishes an exemption from the requirement for a tolerance, under the Federal Food, Drug and Cosmetic Act.

For further information, please visit http://www.epa.gov/pesticides/biopesticides.

Under the Toxic Substances Control Act (TSCA), the EPA acquires information in order to identify and regulate potential hazards and exposures. TSCA applies to the manufacturing, processing, importation, distribution, use, and disposal of all chemicals in commerce, or intended for entry into commerce, that are not specifically covered by other regulatory authorities, (e.g. substances other than food, drugs, cosmetics and pesticides).

TSCA's applicability to the regulation of products of biotechnology is based on the interpretation that organisms are chemical substances under TSCA. The EPA's TSCA Biotechnology Program of the Office of Prevention and Toxic Substances currently regulates microorganisms intended for general industrial uses. The Program conducts a pre-market review of "new" microorganisms, i.e. those microorganisms formed by deliberate combinations of genetic material from organisms classified in different taxonomic genera.) Developers must notify the EPA 90 days prior to manufacture or 60 days prior to field testing of a product regulated by TSCA.

For further information, please visit http://www.epa.gov/oppt/biotech/

Part d. United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) (http://www.aphis.usda.gov/) (All)

Within USDA, the Animal and Plant Health Inspection Service (APHIS) is responsible for protecting agriculture from pests and diseases. Under the Plant Protection Act, USDA- APHIS has regulatory oversight over products of modern biotechnology that could pose such a risk. Accordingly, USDA-APHIS regulates organisms and products that are known or suspected to be plant pests or to pose a plant pest risk, including those that have been altered or produced through genetic engineering. These are called "regulated articles." USDA- APHIS regulates the import, handling, interstate movement, and release into the environment of regulated organisms that are products of biotechnology, including organisms undergoing confined experimental use or field trials. Regulated articles are reviewed to ensure that, under the proposed conditions of use, they do not present a plant pest risk through ensuring appropriate handling, confinement and disposal.

USDA-APHIS regulations provide a petition process for the determination of non-regulated status. If a petition is granted, that organism will no longer be considered a "regulated article" and will no longer be subject to oversight by USDA-APHIS. The petitioner must supply information such as the biology of the recipient plant, experimental data and publications, genotypic and phenotypic descriptions of the genetically engineered organism, and field test reports. The agency evaluates a variety of issues including the potential for plant pest risk; disease and pest susceptibilities; the expression of gene products, new enzymes, or changes to plant metabolism; weediness and impact on sexually compatible plants; agricultural or

cultivation practices; effects on non-target organisms; and the potential for gene transfer to other types of organisms. A notice is filed in the Federal Register and public comments are considered on the environmental assessment and determination written for the decision on granting the petition. Copies of the USDA-APHIS documents are available to the public.

For further information on the petition process, please visit http://www.aphis.usda.gov/brs/.

Under the Virus, Serum, Toxin Act, USDA-APHIS Veterinary Services inspects biologics production establishments and licenses veterinary biological substances, including animal vaccines, that are products of biotechnology.

For further information, please visit http://www.aphis.usda.gov/vs/.

Part d-i: APHIS' Role in Biotechnology (Hooper)
APHIS uses the term biotechnology to mean the use of recombinant DNA technology, or genetic engineering (GE) to modify living organisms. APHIS regulates certain GE organisms that may pose a risk to plant or animal health. In addition, APHIS participates in programs that use biotechnology to identify and control plant[1] and animal[2] pests. Below is a list of the regulatory requirements for genetically engineered organisms and facilities.

1. Introducing Genetically Engineered Organisms that may be Plant Pests:
   i. APHIS' Biotechnology Regulatory Services[3] regulates the introduction (importation, interstate movement, and release into the environment) of genetically engineered organisms that may pose a risk to plant health.
2. Importing or Exporting Genetically Engineered Animals and Animal Products
3. Obtaining Licenses for Veterinary Biologics
4. Obtaining Registration for Animal Facilities
5. Obtaining Other Authorizations from APHIS

[1] http://webdev.aphis.usda.gov/plant_health/index.shtml
[2] http://webdev.aphis.usda.gov/animal_welfare/index.shtml
[3] http://www.aphis.usda.gov/biotechnology/brs_main.shtml" \t "_blank

Part d-ii. **Government Accountability Office Review of Regulation of GE Crops** (Steve Devoto)

At the request of the U. S. Senate Committee on Agriculture, Nutrition and Forestry, the Government Accountability Office (GAO) carried out a review of the USDA, the FDA and the EPA regulation of GE crops. The full review is available at the web site listed in Reference 1 below.[1]

The report states that there have been six known unauthorized releases of GE crops into food, animal feed or the environment beyond farm fields but the total number of releases is unknown. "In 2007, USDA analyzed its record of over 700 violations or potential violations that occurred from January 2003 through August 2007 and found 98 that indicated a possible release into the environment."[2]

In the highlights section the GAO report recommends several actions which could be taken by

USDA, FDA and the EPA to improve their oversight and present more transparency to their work:

1. "FDA (should) make public the results of its ***early food safety assessments*** (emphasis added) of GE crops.
2. USDA and FDA develop an agreement to share information on GE crops with traits that, if released into the food or feed supply, ***could cause health concerns*** (emphasis added).
3. USDA, EPA and FDA ***develop a risk-based strategy for monitoring the widespread use of marketed GE crops*** (emphasis added)."

"FDA agreed with the first recommendation and, with USDA, agreed in part with the second. The agencies agree in part with the third recommendation."

The GAO replied: "We stand by the recommendations."

The GAO also noted that the FDA proposed in 2001 "to require that food developers notify the agency before marketing their products. However, as of July 2008, FDA had not taken action to finalize the proposed rule, believing its current approach calling for voluntary notice is sufficient."

Of particular concern for growers in Lake County, are observations on proximity of GE and non-GE crops."[3]

> "Another concern stemming from the widespread use of GE crops is the economic impact they might have on farmers growing conventional or organic crops. For example, some growers of non-GE crops fear that seeds or pollens containing engineered traits from neighboring fields may commingle with their crops, thereby making those crops harder to sell to customers who prefer not to consume GE products. In this regard, the U.S. District Court of the District of Northern California ruled that USDA needed to conduct an environmental impact statement to analyze, among other things, the impact that deregulating a particular GE alfalfa might have on farmers growing organic or conventional alfalfa. In a 2008 report to the Secretary of Agriculture, USDA's Advisory Committee on Biotechnology and 21st Century Agriculture concluded that fostering coexistence between GE and non-GE crops is an important and worthwhile goal and acknowledged that the proximity of GE crops to conventional and organic crops sometimes cause commingling, preventing some retail consumers from finding products that are free of GE crops. The committee recommended that the Secretary 'take note' of several factors that can cause commingling, such as the failure to adequately contain regulated GE crops."

The GAO report continues:

> "Despite these recommendations and observations from various sources, we found that USDA, EPA and FDA do not have a mechanism to monitor, evaluate and report on the impact of the commercialization of GE crops following the completion of the agencies' evaluation procedures. USDA, the agency with the most comprehensive authority regarding GE crops, has no systematic program of post market oversight. ***Without monitoring, undesirable agricultural and environmental problems could result from the unintended transfer of genetic material from deregulated GE crops to non-GE***

crops and other plants, and these problems could have significant financial implications."[3]

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[1] GAO-09-60 http://www.gao.gov/new.items/d0960.pdf
[2] GAO-09-60, pages 16-17
[3] GAO-09-60, pages 31-32

Part e: California Department of Food and Agriculture (CDFA) (Lorrie Gray)

The California Department of Food and Agriculture (CDFA) is charged with protecting and promoting agriculture. Part of that function is to review APHIS notification and permit applications for genetically engineered crop field trails in the state, and to comment upon them.

GAP: CDFA laboratories do not have access to manufacturer's proprietary information, usually claimed to be Confidential Business Information (CBI).

GAP: California Assembly Bill 541, signed into law in September 2008 requires the CDFA or a CDFA designated independent third party to carry out any sampling activity as specified in California See Law regulations

GAP: AB541 was amended several times before the final language was achieved. Included in the stricken portions were:

1. Requirements for any farmer planning open field production of a genetically engineered plant to notify the agricultural commissioner in the county where production was to occur within 30 days of planting.
2. It would have required said commissioner to include in the annual crop report submitted to the Department of Food and Agriculture information collected during the year on the number of acres of open field production of genetically engineered plants, the types of crops produced, and the genetic traits of those crops.
3. It would have also provided for the Secretary of Food and Agriculture or agriculture commissioner to levy civil penalties against any person who failed to provide the required notice, or who violated the provision of the regulations, in the amount of not less than $500 nor more than $5,000 for each violation.

Part f: Organic Regulations Relative To Genetically Modified Crops (Steve Devoto)

In order to sell a crop as organic, the producer must be certified as organic by a certifier licensed by the USDA National Organic Program (NOP) unless annual sales are less than $5,000. A certifying company often used is the California Certified Organic Farmers (CCOF) which was founded before the national program was started. All certifiers must follow the guidelines in the NOP (see Reference 1 for a link to the web USDA NOP web site[1]).

Regarding GE substances the NOP guidelines include the following sections:

(NOP 205.2) Excluded methods.

A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion,

microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture.

NOP 205.105 Allowed and prohibited substances, methods, and ingredients in organic production and handling.

To be sold or labeled as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))," the product must be produced and handled without the use of:

(a) Synthetic substances and ingredients, except as provided in § 205.601 or § 205.603;
(b) Non-synthetic substances prohibited in § 205.602 or § 205.604;
(c) Nonagricultural substances used in or on processed products, except as otherwise provided in § 205.605;
(d) Nonorganic agricultural substances used in or on processed products, except as otherwise provided
in § 205.606;
(e) Excluded methods, except for vaccines, provided that the vaccines are approved in accordance with § 205.600(a);
(f) Ionizing radiation, as described in Food and Drug Administration regulation, 21 CFR 179.26; and
(g) Sewage sludge."

On the basis of these sections, no GE modified inputs whatsoever may be used in organic production.

The question of the possible contamination of an organic crop by drift of an excluded material has been addressed in a letter from Bill Hawks, Under Secretary, Department of Agriculture:

"The presence of a detectable residue of excluded methods alone does not necessarily constitute a violation of this regulation (NOP 205.2). As long as an organic operation has not used excluded methods and takes reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan, the unintentional presence of the products of excluded methods will not affect the status of the organic operation. As to the status of the commodity, USDA's position is that this is left to the buyer and seller to resolve in the marketplace through their contractual relationship." [2]

Thus, the "contaminated" crop could still be sold as "organic." A letter from Neal MacDougall of the San Luis Obispo Chapter of CCOF addresses the attitude of a buyer of a "contaminated" product.

"...while a grower would still be allowed to sell genetically contaminated product as being certified organic, it is highly unlikely that a buyer of that product (especially if the organic product is an input into a processed organic product) would be willing to buy that product. If it became widely known that a grower's certified organic product is contaminated, the organic status of the product would not be enough to convince buyers that the product is truly equivalent to other organic products that were not similarly contaminated. When such a product is to be exported or it is to be incorporated into an organic product that is to be exported, the danger becomes even greater since foreign buyers and processors are hesitant to purchase product that their customers might think is contaminated."[3]

The NOP provides that buffers should be provided between the organic crop area and conventionally farmed crops. The buffers can prevent or at least minimize drift of non-organic sprays on the organic crop. Such buffers could also be utilized between GE crops and organic crops. The situation is somewhat different in the latter case. While the spray material will only have a transient effect on the organic crop, the GE crop could cause transformation of the crop because of, for example, pollen drift. A study of this effect has been published in the peer-reviewed article by Ellstrand. In studies of hybridization of wild and cultivated radishes he found that hybridization at a level of about 2% occurred when the plants were separated by 0.62 mile (1 kilometer). He also studied the hybridization of two distinct species, sorghum bicolor and Johnson Grass, "one of the world's worst weeds." Hybridization by pollen drift could be detected at a separation of 330 feet (100 meters). This study indicates that it could be very difficult to furnish an adequate buffer between GE and organic crops to allow the latter to have non-detectable levels of GE traits.[4]

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[1] http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?template=TemplateF&navID=Regulations NOPNationalOrganicProgramHome&rightNav1=RegulationsNOPNationalOrganicProgramHome&topNav =&leftNav=NationalOrganicProgram&page=NOPRegulations&resultType=&acct=noprulemaking

[2] Letter from Bill Hawks, Under Secretary, Marketing and Regulatory Programs, December 21, 2004, USDA to Gus Douglass, Commissioner, The National Association of State Departments of Agriculture

[3] Appendix E, Committee Report-Evaluation of Growing GE Crops in San Luis Obispo County, July 19, 2004

[4] Elstrand, Norman C., "When crop transgenes wander in California, should we worry?," 2006, *California Agriculture* Volume 60 Number 3, page 116

Chapter 2: Tracking and Monitoring

(Subcommittee Two: Victoria Brandon, Jeff Gleaves, Sky Hoyt, Andre Ross)

Although genetic purity can never be guaranteed, it seems improbable that identifiable transgenic inputs exist in Lake County at the present time. Transgenic mosaic-virus resistant summer squash is available to commercial growers, and may have been planted here[1]. Since squash pollen travels up to a quarter-mile (see Appendix 7 on Buffer Zones), cross-pollination with non-GE varieties of *C.pepo* is not improbable, but unless the resulting seed was replanted no persistent effect on the genome would occur. Similar considerations apply to the small patch of corn that is the single GE crop known to have been cultivated here: it may indeed have pollinated other corn within a fairly large radius (the Seed Savers Exchange recommends a one-mile buffer zone; see Appendix 7) but the rate of dispersal diminishes rapidly with distance,,[2] and unless these neighboring growers saved and replanted the seed the GE traits terminated in a single generation. Corn has no compatible wild relatives in this region (or anywhere in the United States), and is incapable of establishing feral colonies[3]. If GE alfalfa hay has been imported into Lake County (something which cannot be determined) and subsequently persisted as a volunteer, some remnants of the engineered genome might continue to exist, with the potential of reproducing ferally, but even though these plants would contain a glyphosate-resistant gene that confers an adaptive advantage, their extreme scarcity would make their continuation in the genome improbable from a statistical perspective. Lake County's geographic isolation makes the presence of other GE influences still less likely.

If additional GE crops are cultivated here unintended consequences will vary on a case by case basis. For example, a plant engineered to produce sterile pollen (as has been proposed for a crown gall-resistant walnut rootstock now in development[4]) would not be expected to have any effect at all on either the cultivated or compatible wild genome. On the other hand the genetic influence of a plant (such as canola) which has pollen that travels long distances and a propensity to interbreed with a number of related species[5] would be to all intents uncontrollable. A number of considerations should be evaluated in assessing the probability of unwanted gene flow, including the geographical distance of pollen drift (Appendix 7), the structure of the flower (for example, soybeans self-pollinate before their blossoms even open), whether the plant is a biennial normally harvested before flowering, or otherwise unlikely to reproduce, the probability of viable seeds persisting in the field, or being spread by natural means, the degree of adaptive advantage conferred by the genetically engineered trait, and the existence of non-GE crops, feral populations, or compatible wild relatives in the vicinity.

Nor is the possibility of unintended gene flow limited to accidental cross-pollination. Numerous instances have been documented of intermingling of seeds, entry of products not intended for human consumption into the food chain, and shipment of GE crops to markets which bar them.[6] Management of test plots of crops not yet approved for commercial distribution is particularly problematic, since APHIS does not routinely track compliance of permit holders, review containment protocols, or evaluate harmful effects on the environment.[7]

In order to minimize potential hazards while simultaneously enjoying the advantages that some GE products may offer, the special characteristics of each must be considered. Many if not all may require registration, under conditions imposed to minimize gene flow or trait-specific adverse consequences such as the creation of herbicide-resistant weeds. Since the likelihood of adverse effects on neighboring growers will vary according to the nature of the neighboring agricultural operations, information about the existence of GE crops in the vicinity must be made

publicly available. Transparency and trust would also be improved by maintaining a voluntary registry list of individuals who wish to be notified of any new proposals for cultivation. Grower anxiety about the possibility of confrontational activism, perhaps even extending to vandalism[8], is another subject that should be addressed: farmers who comply with a permit/notification process must be assured that their right to the peaceful enjoyment of their property will be strenuously protected. When conflicts exist, as seems inevitable, the principle "first in time, first in right" could be considered as part of an equitable resolution.

If Lake County adopts a regulatory structure to manage the introduction of GE crops, it must also devise a protocol to qualify a given crop as safe. Aside from evaluating the probability of unintended gene flow as detailed above, such a protocol should include an evaluation of the benefits conferred by the crop in question, possible hazards to other growers or the environment, and the means for achieving legal and economic redress should harm occur to others. The operations of such a structure should also be completely transparent to growers and other concerned citizens, and to the extent feasible minimize both administrative costs and interference with individual freedom of action.

Other possibilities that the subcommittee believes should be considered include

- monetary compensation for farmers who can conclusively demonstrate economic loss by being unable to grow a GE crop, possibly funded through a fee imposed on agricultural land that is converted to other uses
- a recommendation that the Board of Supervisors ask our legislators to pursue a national labeling law for GE crops, and the manufactured products that contain them
- a recommendation that the Board of Supervisors ask our legislators to promote periodic review of the "substantially equivalent" designation, and the systematic conduct of rigorous and objective studies on the long-term health effects of GE products.
- a recommendation that the county review its purchasing policy to favor non-GE products to the extent that these are identifiable and competitive

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Notes, Tracking and Monitoring

[1] NBIAP News Report." U.S. Department of Agriculture, "Genetically Engineered Virus-Resistant Squash Approved For Sale" http://www.accessexcellence.org/RC/AB/BA/Gen_Engineered_Squash.php (January 1995); Cornell University, Yellow Summer Squash Disease Resistance Table, http://vegetablemdonline.ppath.cornell.edu/Tables/YellSquashTable.html

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Chapter 3: Economic Impacts

(Subcommittee Two: Victoria Brandon, Jeff Gleaves, Sky Hoyt, Andre Ross)

Genetically engineered (GE) crops dominate many segments of American commodity agriculture: nationwide, it is estimated that 80 percent of corn, 86 percent of cotton, and 92 percent of soy include one or more GE traits, of which glyphosate-resistance and *Bacillus thuringiensis* (Bt) expression are by far the most common.[1] This domination has occurred even though a number of foreign markets are closed to GE products, either by banning them outright or by imposing labeling requirements. Markets for GE crops are limited further by their complete exclusion from products defined as organic, and by the decision of a number of food manufacturers ranging from Gerbers[2] to Trader Joe's[3] to reject GE ingredients. As a result, non-GE commodities can enjoy a price advantage: for example, the April 14, 2009 Chicago Board of Trade price for GE soybeans ranged from $9.30-$10.28/bushel, with non-GE soybeans receiving a premium ranging from $.55-$1.80 depending on variety.[4] The subcommittee did not attempt to analyze differentials in yield, production costs, or net returns for these crops.

Since the GE-free price advantage is market driven, and originates primarily in public perception of the unhealthfulness of GE foodstuffs, the introduction of labeling requirements in the United States would probably result in an increased differential.

In Lake County, where growers depend on niche as well as commodity marketing, the situation is very different. Although it is impossible to be certain, it is believed that only one GE crop (a plot of ornamental glyphosate-resistant corn grown for at least one season) has ever been planted here. Furthermore no GE varieties of our dominant crops —grapes, pears, and walnuts—are available, although several products are currently in the research stage. At the present time, the GE crop with greatest probability of being planted in Lake County is corn. Both Bt and glyphosate-resistant corn offer practical advantages to the producer (especially Bt corn which would provide a simple way to avoid damage from earworms and borers (see Appendix 9 analyzing earworm control techniques and comparative costs), but since locally grown corn is also sold locally, primarily through farm stands and farmers markets, widespread consumer resistance can be expected to substantially reduce the incentive to grow it. Similar conditions apply to the numerous commercially-available varieties of mosaic-resistant summer squash. If future GE crops are developed for disease resistance, nutritional enhancement, or ornamental improvement these may arouse different categories of public perception than Bt and glyphosate-resistant products.

Looking into the future, introduction of GE varieties of both alfalfa and grass hay is probable within the next few years. GE alfalfa seed was commercially available several years ago, and some stands of this perennial crop are still in production (outside Lake County) although additional plantings were halted by the courts in 2007, pending environmental review now nearing conclusion. GE grass hay remains in the research and development phase, but commercial release may occur within five years. Local demand would probably materialize once either or both of these products was available. Research on GE walnuts[5] and grapes[6] may also result in a marketable product within the next five years, with development of GE pears[7] far less likely in the foreseeable future.

The economic benefits of planting GE crops vary with the crop in question, as do the possible disadvantages (see Risks and Benefits table for details), but the most significant potential risk

applies to all: if a non-GE crop is inadvertently pollinated by a GE variety, or if intermingling occurs during distribution, the marketability of the non-GE crop could be reduced.

This is especially true of organic crops, which enjoy a significant price advantage: in 2008 the wholesale price of Lake County organic walnuts was around $2.50/pound, conventional between $1.10-$1.40. Organic pears sold for processing brought $350/ton, and prime organic pears for the fresh market $550 and up, compared to an average of $200 per ton for conventionally-grown pears at the sheds.[8] Producers who sold directly to the public got much more: for example the Lake County Community Co-op was selling local organic walnuts at more than $6/pound. Organic standards allow for no admixture of GE inputs whatsoever, not even on a *de minimus* level. Loss of organic certification in the case of accidental gene flow does not appear to be an issue, nor does genetic drift into a cover crop not intended for sale or human consumption (even if the main crop is organically grown), but inability to market an organically-grown crop as organic would entail a significant financial loss for the grower, to the extent that some organic farmers might prefer to avoid purchasing land anywhere near an area where GE crops are cultivated. The same consideration applies to a conventionally grown crop that is designated for a "GE-free" niche market.

Growers who sell locally, with a direct connection to their customers, face another hazard if any GE crops are cultivated in their vicinity, even if cross-pollination is not a possibility. Some consumers have such a strong negative perception of genetic engineering in general that the possibility of mere pollen drift could result in a form of "negative advertising" resulting in diminished sales. Since this effect would be very hard to measure, the possibility of recovering compensatory damages from the GE grower would be much less than that resulting from reduced marketability because of verifiable pollination.

Additional risks accompany the cultivation of pharmaceutical GE crops. If these are grown in open field conditions and any pollination of neighboring conventional or organic crops occurs, or intermixture during distribution, they could become completely unsalable, and in some cases even dangerous to human health.[9] Special considerations also relate to beekeepers[10], effects on invasive weed management[11], and Lake County's public image. See the chart for details

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Notes, Economic Impacts

[1] Jorge Fernandez-Cornejo, "Rapid Growth in Adoption of Genetically Engineered Crops Continues in U.S." *Amber Waves: the economics of food, farming, natural resources, and rural America* (September 2008). http://www.ers.usda.gov/AmberWaves/September08/Findings/GECrops.htm

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[3] "Trader Joe's to GMO's: Go!" (January 1 2002); http://www.allbusiness.com/retail-trade/clothing-clothing-accessories-stores-stores/110131-1.html

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[7] http://www.gmo-compass.org/eng/database/plants/22.pear.html

[8] Private communication from local grower

[9] http://www.gmo-compass.org/eng/news/stories/205.farm_fresh_pharmaceuticals.html

"UCS Uncovers Lax Oversight of Pharma Crops," Union of Concerned Scientists, http://www.ucsusa.org/food_and_agriculture/solutions/sensible_pharma_crops/ucs-uncovers-lax-oversight-of.html

[10] Will Dunham, "Commercially Engineered Bees Spread Disease to Wild Bees," (July 23, 2008), http://www.commondreams.org/archive/2008/07/23/10550

[11] Brenda Carol, "Preserving glyphosate efficacy vital to San Joaquin Valley growers," *Western Farm Press* (Feb 25, 2009) http://westernfarmpress.com/cotton/glyphosate-resistance-0225/

Risks and benefits of genetically engineered crops to local growers, consumers, and the larger community

Producers

	risks	benefits	comments
Wine grapes[1]	Winery/consumer resistance to GE[2] Inadvertent GE pollination could affect marketability	Pierce's disease and leafroll-free grapevines in development	
Pears	Pear sustainability management plan now requiring "GE-free" attestation		No GE pears exist or are expected any time soon[3]
Walnuts	Walnuts produce abundant pollen that travels long distances, and the crop *is* the seed. GE pollination could destroy price advantage enjoyed by organic growers	Crown gall-resistant rootstock in development[4]	
Market gardens	Strong resistance among some consumers, who buy directly from producers Pollen drift from neighboring GE crop could adversely affect perception of product leading to diminished sales*	Bt corn free of earworms/corn borers (see Appendix 9) Bt and Roundup Ready corn (and other garden crops now in development) may be easier to grow Summer squash varieties resist mosaic diseases	

* this potential harm from "negative advertising" (possibly in the form of rumor) applies to any grower selling to a local market, where the existence of an adjacent GE crop could become known

Producers (continued)

	risks	benefits	comments
Pharmaceuticals[5]	If field grown, GE pollination of either conventional or organic crops could make them not merely unsalable but possibly dangerous to human health	Opportunity to grow high-value crop if safety issue can be addressed	
marijuana			The subcommittee heard rumors about the existence of GE medical or recreational cannabis but without further information was unable to investigate the subject
Soy, canola			Possibility of growing non-GE variety in Lake County
Hay (alfalfa, wheat grass, etc)	increased creation of resistant weeds if herbicide-resistant alfalfa or other hay crops are grown** possible gene flow into feral alfalfa or other wild plants including grasses (in the case of grass hay) possible gene flow into poultry pastures or trap crops used in horticulture some livestock owners would be unwilling to feed GE products to their animals	Glyphosate-resistant alfalfa (if allowed by courts) could provide extra weed-free cutting, and may be seen by some farmers as easier to grow GE grass hay might be cheaper to produce Glyphosate-resistant crops may be safer to farmworkers and the environment than other herbicide programs[6]	

** creation of herbicide resistant weeds is an issue with overuse of *any* herbicides, but cultivation of transgenic glyphosate-resistant varieties has been known to greatly exacerbate the problem.[7]

Producers (continued)

	risks	benefits	comments
Beekeepers	Introduction of GE greenhouse bee could materially impact both wild and managed colonies [8] Some GE products contain pesticides that could harm bees, leading to loss of hives (economic harm to beekeepers) and loss of essential pollinators (harm to growers) ***		
other			GE-free area in Lake County could provide opportunity for production of non-GE seed

*** this risk does not appear to apply to Bt crops [9]

Consumers

Sweet corn	Possible pollination of conventional or organic corn could make local non-GE corn hard to find: long distances traveled by corn pollen makes this effect more probable	Bt variety free of earworms	
Cattle, horses, sheep, etc	Possible consumer resistance to animals fed GE hay	Increased supply of weed-free hay, possibly at lower cost	"branding" of Lake County grassfed beef as GE-free could provide a selling point and possible price advantage

The community as a whole

	risks	benefits	comments
Lake County's image	Impeding "green/clean" image to detriment of tourist industry as well as agriculture	Seen as farmer-friendly (but not all farmers)	Opposite effects from comprehensive GE regulations (if well-publicized as part of a coordinated marketing plan)
Invasive weed management	Evolution of herbicide resistance (if herbicide-tolerant products are grown)****		
Agricultural real estate	Possibility that land where GE-crops are grown could become ineligible for future organic certification	Ag land prices could rise if GE varieties led to new opportunities or better margins	
Soil microorganisms			The subcommittee considered the allegation that GE crops (particularly Bt crops) could adversely affect soil microorganisms but found the standard of evidence in cited studies unpersuasive[10]

****see comment on herbicides above

Notes. Economic Risks and Benefits

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[2] Alan Goldfarb, "Will Napa Valley Grow Genetically Modified Grapevines?" AppellationAmerica.com (July 5, 2007) http://wine.appellationamerica.com/wine-review/434/GMO-grapes.html

[3] http://www.gmo-compass.org/eng/database/plants/22.pear.html For more information on this subject related specifically to Lake County, see "Other Considerations" at the end of the next chapter (page 25)

[4] "Walnut Improvement Program" Grant Proposal, University of California, Division of Agricultural Sciences. Available at http://www.co.lake.ca.us/Government/Boards/AdvisoryBoard/Genetically_Engineered_Crops_Advisory_Committee/Recommended_Reading.htm. See also http://archives.foodsafety.ksu.edu/agnet/2004/5-2003/agnet_may_6-2.htm

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[6] Michele C. Marra, Nicholas E. Piggott, and Gerald A. Carlson, "The net benefits, including convenience, of Roundup Ready soybeans," NSF Center for IPM Technical Bulletin (September, 2004). For a different perspective see "Genetically Engineered Sugar Beets" (3/10/07), Cases We Are Working On, http://www.earthjustice.org/our_work/cases/?issue=27448764&region=27448848

[7] ScienceDaily (May 27, 2009); "Herbicide resistant crops," GMO Compass, http://www.gmo-compass.org/eng/agri_biotechnology/breeding_aims/146.herbicide_resistant_crops.html

[8] Will Dunham, "Commercially Engineered Bees Spread Disease to Wild Bees," (July 23, 2008), http://www.commondreams.org/archive/2008/07/23/10550

[9] Dirk Babendreier, Birgit Reichhart, Jörg Romeis & Franz Bigler, "Impact of Insecticidal Proteins Expressed in Transgenic Plants on Bumblebee Microcolonies," Agroscope Reckenholz-Tänikon Research Station ART, Reckenholzstrasse 191, 8046 Zürich, Switzerland (2007); "Bees and GM plants," GMO Safety, http://www.gmo-safety.eu/en/oilseed_rape/honey_bees/339.docu.html

[10] http://www.navdanya.org/news/25feb09.htm; http://www.i-sis.org.uk/horizontalGeneTransfer.php; http://www.psrast.org/soilecolart.htm). For fact-based arguments see Saxena and Stotzky, "Bacillus Thuringiensis (Bt) Toxin Released from Root Exudates and Biomass of Bt Corn Has No Apparent Effect on Earthworms, Nematodes, Protozoa, Bacteria and Fungi in Soil," *Soil Biology & Biochemistry* 33 (2001) (January 2001), Dunfield and Germida, "Impact of Genetically Modified Crops on Soil- and Plant-Associated Microbial Communities, *Journal of Environmental Quality* (2004), http://jeq.scijournals.org/cgi/content/abstract/joenq;33/3/806, and Griffiths et al, "Soil Microbial and Faunal Community Responses to Bt Maize and Insecticide in Two Soils," *Journal of Environmental Quality* (2005) http://jeq.scijournals.org/cgi/content/abstract/35/3/734

Chapter 4: Environmental Impacts

(Subcommittee Three: Glenn Benjamin, Lars Crail, Steve Grammer,
Paul Lauwenroth, JoAnn Saccato, Broc Zoller)

Introduction

The Environmental & Liability Subcommittee (ELS) was charged with the task of reviewing the information on the impact of GE crops in the environment at large. In addition, the subcommittee spent extensive time with regards to the specific potential impact of GE crops to other commercial growers, specifically organic, in Lake County, and investigating the possible avenues to address such issues.

The following grid is a summary of issues discussed by the ELS to date. This report is not intended to be a comprehensive report of all environmental issues with GE crops. It is well understood that because of the nature of the ecosystem being complex and inextricably intertwined, there will be an interaction and impact as a result of GE introduction into the environment. While there is some information regarding the consequences of the interaction, conclusive evidence is lacking due to the absence of long-term studies specifically targeting the impact on the larger environment.

The information in the grid is broken down into categories of Benefit, Risk, or Not Applicable (NA), whether the benefit or risk is Potential (P) or Actual (A) with sources cited in parentheses as documentation of claim, and whether the subcommittee is in Total Agreement (TA) or Not In Agreement (NIA) on that aspect of the issue. Each issue, benefits and risks are sourced with the pertinent studies the subcommittee reviewed as a part of their task.

Benefit	***P***	***A***	***TA***	***NIA***	***Risk***	***P***	***A***	***TA***	***NIA***	***NA***	***Notes***
Disease Resistance	X (6, 25, 26, 29)	X (6)	X								
Drought Tolerance	X (25, 26, 42)										
Low soil oxygen tolerance	X (25, 26)										
Adaptability in deficient nutrient situations	X										

Benefit	*P*	*A*	*TA*	*NIA*	*Risk*	*P*	*A*	*TA*	*NIA*	*NA*	*Notes*
Atmospheric nitrogen utilization	X										
Less applied nutrients resulting in less environmental impacts.	X										
Reduced use of water, nutrient additions, & fuels*	X (6)	X (8, 33)									*In comparison to non-GE, non-organic crops
Increased nutritional content of food	X (6, 31, 32)	X (6)									
Increased crop productivity	X (6, 25, 26)	X (6, 8, 33)		X	Decreased crop productivity	X	X (2)		X		
New sources of pharmacological, energy, & industrial products*	X (6, 19, 25)	X (6, 8)	X		Unintended release of pharmacological, industrial crops and heavy metal accumulators into the environment	X	X (18, 25, 26)	X			*Potential reduced impact imposed by synthetic sources
Increase in biodiversity	X			X	Loss of biodiversity	X			X		
Decrease in pesticide use	X (6)	X (8)		X	Increase in pesticide use	X	X (4, 21, 24)		X	X *	*Some plants are not bred for pesticide-related traits.

Benefit	*P*	*A*	*TA*	*NIA*	*Risk*	*P*	*A*	*TA*	*NIA*	*NA*	*Notes*
					Development of pest (weed) resistance via selection pressure from repeated herbicide applications	X	X (19, 27, 4, 21, 10, 24, 26)		X		
Some native species benefit from expressed traits	X		X		Some native species and/or soil bacteria fluctuate in populations from expressed GE traits	X	X (23, 7, 26)	X		X **	*A natural occurring process through pollination, either by drift or carrier **Cases where no gene flow occurs because pollen of GE crop could be sterile or there may be no wild relatives pollinated by GE crop
Some undesirable* native and non-native populations decrease	X		X		Some undesirable* native and non-native populations increase	X	X (22, 30, 24)	X			* Undesirable is a value judgment.
Changed characteristics of native species positively impact the food web	X		X		Changed characteristics of native species negatively impact the food web*	X	X (14)	X		X	*Some plants/animals may lose food sources as a result of gene flow introduction into native species that result in changed characteristics
					Adventitious presence* in crop results from commingling and/or gene flow	X	X (24, 26)		X		*"Unwanted substances unavoidably present in production and marketing of agricultural products." (24)

Benefit	*P*	*A*	*TA*	*NIA*	*Risk*	*P*	*A*	*TA*	*NIA*	*NA*	*Notes*
Positively affect a beneficial non-targeted species' population	X (26)		X		Detrimentally affect a beneficial non-targeted species' population	X	X (36, 44, 17, 28, 37, 24, 3, 26)	X			
					Some plants and/or animals have shortened life span and loss of necessary habitat	X (26)			X		
					Unknown impacts of unintended movement of transgenes into new hosts	X	X (24, 41, 26)		X		
					Horizontal Gene Transfer* to non-target soil bacterium	X (26)	X (15)		X		*Gene flow to unrelated species
					Supports monoculture	X	X (1)		X		
					Irreversible negative impacts from release of GE organisms	X					

Summary

The ELS was in agreement that the intention is to not inhibit the Lake County farmers' ability to grow and market their crops, except when the practices damage the environment and/or jeopardize public health.

There was agreement by the ELS that overuse of pesticides can damage the environment. While a myriad of traits have the possibility of expression through GE technology (see table above for potential and actual trait expression), the majority of currently marketed GE crops express

pesticide related traits, such as herbicide tolerance (HT) and *Bacillus thuringiensis* (Bt). (25, 26) While studies indicate that a decrease in pesticide use may occur in HT crops (8, 25), studies also indicate that there may be an eventual overall increase in pesticide use due to varying factors that include the increased acreage of planted HT crops as a contributing factor, as well as the eventual resistance developed by the weeds that may result in increased application of the pesticide. (4, 21, 24). It should be noted that studies referenced do not apply an equal set of criteria and/or data points making comparisons and conclusions difficult. (24)

There was agreement by the ELS that overuse of fertilizers (organic and synthetically produced from fossil fuel sources) can damage the environment. Some hope in GE technology is in the arena of reduced energy, nutrient and water inputs. Some members of the subcommittee believe that current agricultural methods available can address these issues. One study indicated that organic methods of production use 28-32% fewer energy inputs. (34) Further, for example, one potential trait for GE expression is drought tolerance. While this is an important factor in agriculture, and may be even more important as we move forward with current global resource challenges, current information on organic methods indicate that organic methods alone can improve yields sometimes up to 34%, during drought conditions. (34) Some members of the subcommittee believe that since current available methods of agricultural production can mitigate some of the agricultural challenges of today, GE technology is not a necessary, but rather, a novel technology, and question whether the impact on the environment (potential and actual) is worth the risk. Similarly, these members also believe that the burden of proof for safety, health, environmental risk and benefit should be born by the proponents of GE technology.

Transgenic traits have different probabilities for the natural selection process to transform a crop into an unmanageable "weed" or "volunteer". According to research, the herbicide tolerance (Ht) trait has a medium potential (19). In addition, industrial compounds and plant-made pharmaceuticals have a medium to high probability that off-site gene flow would create significant adverse human health/nutrition impacts. Overviews of the current pathway of biotech organisms through the U.S. regulatory system are further discussed by Gealy et al. (19) and Lemaux (25, 26).

In 2006, the USDA Advisory Committee on Biotechnology and 21st Century Agriculture (USDA CB2CA) issued a report with the following statement, "There is a need for more publicly sponsored data collection and peer-reviewed analyses on the use and broad impacts of transgenic organisms. Such data and analyses should be publicly available" (39). The ELS agreed that a constant monitor and review is necessary, as new information on GE technology is ever-evolving, and believed that GE crops need to be evaluated on a case-by-case basis as bred characteristics and traits may or may not have an impact on the environment. The ELS realized that they don't necessarily have confidence in the bias of some of the studies referenced, and thus, don't have confidence in the contents of some of the studies. It has recently been suggested that the ability to study GE organisms within the commercial crop system has been hindered by the desire of the GE agricultural industry to protect its proprietary interests (35).

It is widely understood and accepted that gene flow occurs not only in non-biotech crops, but in biotech crops as well (19). Seed dispersal has also led to transgenic feral populations of *Brassica napus* (canola) beyond agricultural fields (19). In addition, anecdotal evidence shows that ripe alfalfa seed eaten by grazing animals can be excreted and are capable of germination (40). Given proposed and implemented approaches to mitigation efforts to eliminate contamination episodes,

no method, or combination of methods, is likely to be 100% successful under all possible scenarios (19). There have been numerous contamination events in the commercial GE world, either through gene flow or seed mixing (i.e. commingling) (11,19). Therefore, some members of the ELS believe that a *de minimus* level of contamination should be accepted. Others believe that since GE is a novel technology, the burden for no contamination rests with the new technology. There was disagreement by the subcommittee whether commercial and/or private growers, the consumers, and the environment should have an expectation or right to "zero" contamination from GE products, with some members strongly committed to this idea. Some members of the ELS think that Lake County regulation of GE crops should be based on scientific studies of pollen mediated gene flow, which suggest that proper buffer distance selection can result in *de minimus* levels of such movement (19,40).

Any presence of GE contamination in the organic food supply is not accepted. The USDA CB2CA admits than even those organizations that have adhered to regulatory procedures, adventitious presence can still occur. In addition, they believe that "the federal government has not set forth comprehensive policies, guidelines or standards" for adventitious presence (39). While organic status of a grower may not be revoked as a result of accidental GE contamination, the crop that incurred contamination may be rejected in the organic market, thus creating an economic deficit for the organic grower. Some world markets have adopted *de minimus* standards (<0.9%) of adventitious presence of approved GE products in non-GE products (12,13,16,19). Since there are no current levels of acceptance in the organic industry, the cumulative affect of an accepted *de minimus* standard may eventually affect the organic industry in Lake County.

Further at issue was whether GE techniques can be precise enough to only affect the traits and conditions desired, or whether other genetic factors will be modified as a result of the technology. For a review of literature pointing to the lack of precision issue of the technology, refer to Wilson (43); also see Lemaux (24,25).

In the case of the three top produced Lake County crops, wine grapes, pears and walnuts, there are only two native species capable of cross pollination (California Wild Grape, *Vitis californica* and Northern California Black Walnut, *Juglans hindsii*) whose impact from the potential gene flow from introduction of GE products would need to be considered in a review process (5). In the case of pear, no native species capable of hybridization are thought to exist (5). In the case of nursery crops in Lake County, the fourth most valuable plant commodity, the particular situation varies with crop. In the case of the wine grape and walnut nursery production industries, the species listed above apply. For other nursery production, each species would need to be considered separately.

In the case of field crops, the situation is also variable by particular crop. In the case of alfalfa, which is an introduced species for example, no native species capable of hybridization are thought to exist in the U.S. (40). In the case of corn, there are no sexually compatible wild relatives in the U.S. or Canada (19). In the case of oats, at least two species (Slender Wild Oat, *Avena barbata* and Wild Oat, *Avena fatua*) may be capable of cross pollination, but this must be verified. These, however, are introduced species, not native (5).

The ELS agreed that each main GE crop introduction in Lake County would need to be considered on a case-by-case basis to evaluate impacts to native species and the environment as a whole. But, the ELS diverged in agreement with regards to all other cultivated GE products.

Because scientific studies suggest the unlikelihood of exceeding de minimus standards of gene flow in widely dispersed plantings (40), some disagreed with the need for Lake County to augment the existing regulatory framework in the case of small acreage crops grown. Others believed that the purview should include all cultivated GE products (e.g. turf grass, small niche market crops, etc.)

Other Considerations (Statements made by individual subcommittee members)
In the case of the three top produced Lake County crops, wine grapes, pears and walnuts, specific scion varietal GE products for various reasons are not likely to be grown in the near future. One reason is buyer resistance to new varieties, in general, and the long time and cost needed to develop a new orchard or vineyard. But there is also specific buyer resistance to GE commodities, because of current perceptions. In the case of pears, this resistance currently includes rootstock choices, even though no gene flow occurs between rootstock and the scion variety grown for sale (9). There also are no existing GE scions or rootstocks for pears. In the cases of the other two crops, GE scion varieties are not available, but GE rootstocks are in the research phase (20,29). Their development is on a slow track because of public perception of GE, and eventual use by growers, if the products prove useful, will depend on buyer approval. It is thought that the potential benefits (listed in the above table) of improved rootstocks for the perennial crops produced in Lake County will make GE rootstocks an eventual well-accepted use for many reasons, if public perception and buyer acceptance changes.

Agreement was held in the ELS that the GE issue will be market-driven.

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Chapter 5: Liabilities

(Subcommittee Three: Glenn Benjamin, Lars Crail, Steve Grammer, Paul Lauwenroth, JoAnn Saccato, Broc Zoller)

The Environmental & Liability Subcommittee (ELS) was charged with the task of reviewing the information on the liability issues surrounding the cultivation of GE crops.

According to the Santa Cruz Public Health report on GE technology[1], liability may be established through statutory or common law. There are two issues the subcommittee inquired into, that of contamination of a farmer's crop by genetic drift and that of patent infringement by a farmer to the patent holder.

Contamination through drift, horizontal gene transfer (HGT) or commingling – Market issues

Currently, there are no statutory laws protecting farmers from GE contamination. Today, the only recourse for farmers whose crops are contaminated is through the civil law system. The organic agriculture industry as well as the California Rice Commission has no acceptable level of contamination, meaning that the grower may lose a price premium or the full sale of a crop if any level of GE material is in the crop. Currently, the burden for redress is on the farmer whose crop has been contaminated through the civil court system. Civil recourse can be time intensive and costly to the farmer, and even more so for the small farmer when faced with large bio-tech industry. Lake County is comprised of smaller-sized farms where these issues may have significant impact.

Organic certification of a farm is not at risk for accidental contamination.

Contamination through HGT – Patent infringement issues

Up until recently, patent infringement issues have been left to the civil court system and many lawsuits have been initiated by patent holders against farmers, even in cases where unintentional contamination has occurred. These cases can be costly, lengthy, and the burden is on the farmer in question to prove there was not the intent for patent infringement.

California enacted AB541 in 2008. It is designed to protect the contaminated grower from lawsuits by the patent holder of the GE crop, though has not been tested in the court system as of this writing. AB541 also establishes a mandatory crop sampling protocol to be used by patent holders when investigating farmers they believe may have violated patents or seed contracts.[2]

California Health & Safety Code Sec. 52305 now provides: "A farmer shall not be liable based on the presence or possession of a patented genetically engineered plant on real property owned or occupied by the farmer when the farmer did not knowingly buy or otherwise knowingly acquire the genetically engineered plant, the farmer acted in good faith and without knowledge of the genetically engineered nature of the plant, and when the genetically engineered plant is detected at a de minimis level. The authority of a court to determine the presence of de minimis levels of a genetically engineered plant is intended solely for the purpose of assisting in adjudicating claims relating to the possession or use of a patented genetically engineered plant in which the seed labeler, patentholder, or licensee, has rights."

This legislation does nothing to help the farmer whose crop has been contaminated and has incurred a loss in the marketplace or otherwise.

Other issues for consideration

According to Anita Grant, County Counsel for the County of Lake if Lake County empowers a regulatory body for GE crops, the County could be held liable for any mandated restrictions on GE crops that attempt to supercede existing regulation:

> There could be a potential for liability if any regulation or protocol was implemented in contravention of existing statutes or if adherence to a regulation and/or protocol created a danger which would not otherwise exist. Depending upon the type of regulation and/or protocol, the County could protect itself from liability to some extent but could not immunize the farmer. [3],

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Notes, Liabilities

[1] Genetic Engineering (GE): A Report from the GE Subcommittee of The Public Health Commission (2006). (p. 56). Santa Cruz County: County of Santa Cruz Health Services Agency. Retrieved from http://www.santacruzhealth.org/ge/

[2] http://www.leginfo.ca.gov/pub/07-08/bill/asm/ab_05010550/ab_541_bill_20080927_chaptered.html

[3] Grant, Anita. Email correspondence dated June 9, 2009

Chapter 6: Health

(Subcommittee Four: Melissa Fulton, Larry Heine, Sequoia Lyn-Franklin, Michelle Scully)

by Larry Heine and Sequoia Lyn-Franklin

NOTE: this Chapter has not yet been approved by the subcommittee or reviewed by the full committee

The subcommittee of Religious, Social/Ethical and Health Issues as related to GE products split the studies into 3 groups and the relation to GE in those areas. Religion was the first, Social/Ethical was second, and Health the third. In the previous reports the attempt was to show without prejudice both sides of the arguments for and against GE food products, just reporting in a neutral fact gathering report those points most used in how positions have been arrived at by those involved. This health report will attempt to do the same.

In studying Health and the relation to GE products much effort was spent trying to find long term health studies related to what effects GE has on humans. None could be found. Time constrains placed on this committee for a final report, and the main arguments within a particular aspect could not all be covered. The effects of GE food on other species should also be included in this report, but time does not allow for that research to be done.

Because GE is used in a wide context this committee had to define what specific GE foods are in this report. Therefore this report is focused on one type of Food Engineering. Engineering plants through gene modification.

This type of plant modification is done through the introduction of a gene from one species into another called "transgenic," using a recombinant-DNA. This technique uses a biological vector, a plasmid or viral chromosome into whose genome a fragment of foreign DNA is inserted, to introduce foreign DNA into a host cell.

There are two main arguments against the use of transgenic in food plants. Allergies and Antibiotic resistance are one. The other is transforming a food plant thru transgenic modification, a Cologne University study in 1998 showed that DNA from such a source fed to mice did survive the digestive system and invade other cells.

Because the FDA and the USDA do not require the labeling of GE foods, it hides the difference between GE and non GE foods. The FDA does not consider genetically engineered foods as food additives as long as they come from an approved food source. Protein content and gene makeup of GE plants in comparison to non GE plants are different. Proteins that have been introduced bring with them into the host plant those allergens which existed in the introduced protein. An example would be a GE soy product that has had a trait added from a milk protein would cause an allergy to someone who is allergic to that milk protein and the source of the allergic reaction would not be known. This is consistent throughout all foods. The danger being without proper food studies and labeling to allow the consumer the choice, the increase in allergies to food for a large portion of the population may continue to grow. It should be noted that those traits are identifiable and precaution can be taken to substantially reduce those occurrences, and with proper labeling avoided.

Antibiotic resistance is a major concern in GE foods. One of the ways to genetically modify plants is the use of the npt11and bla genes. These particular genes confer resistance to antibiotics. This resistance to antibiotics in GE foods taken with antibiotics, produce enzymes that would reduce the effectiveness of the antibiotics taken. Without labeling a person taking antibiotics has no idea if the food source is diminishing the antibiotics being taken. Those same genes from GE foods could be transferred to human or animal pathogens making them impervious to antibiotics. Although unmediated transfers of genetically modified material from plant to bacteria is unlikely, a Cologne University study in 1998 showed that DNA from such a source fed to mice did survive the digestive system and invade other cells.

The concern of using this type of transgenic gene, would be the building of antibiotic resistance in young whose bodies have not yet developed strong immune systems, and others who may have weak immune systems. This is of particular concern for developing nations where nutrition is often suspect and immune systems are not well developed.

The second major concern is using transgenic for the development of food producing plants that are altered to produce toxins. While this plant type has greater ecological concerns, it is in the health report because the toxin *Bacillus thuringiensis* is in the food, not just in the plant. This toxin is a pesticide and the health risks are real. Starlink corn a Bt product was removed from the market by the EPA because of health concerns. It had a protein Cry9C which the EPA did not accept as safe. The FDA and USDA had approved this corn, and it had been on the market for two years before it was determined unsafe and removed. Starlink removed the corn from the market and it is no longer grown. Other Bt crops are still being grown commercially, none in Lake County.

The arguments for transgenic foods is offered by the industry which promotes its use. Industry states Not all GE crops are the same. Inadvertent creation of allergens or toxins is not limited to GMOs, but also occurs by classical breeding technologies (5), and likely also by same species transgenic manipulations. Indeed, introduction of unmodified "natural" Kiwi fruit to U.S. markets in the late 1960s was associated with unexpected cross-reactions with latex rubber (5). This suggests that natural selection, classical breeding techniques, and GE food creation may all have a risk of introducing potential new allergens. Conversely, GE could be used to reduce or eliminate specific allergens plus:

- Value-added output traits, such as corn with higher amounts of lysine for animal feed, or vegetable oils with increased levels of omega-3 fatty acids.
- Drought and salinity tolerance
- Increased yield
- Tool toward diminishing environmental impact of agriculture (ex. China . . .) and
- Creation of nutritionally enhanced foods ex. Vitamin A.

The World Health Organization has proposed nutritional well-being efforts, one of which is the development of fortified rice plants.

It is also promoted by science departments from major universities in the United States. The same universities are funded by the Biotech industry. Within the United States, bio-tech companies which promote GE products as safe, have produced no independent peer reviewed studies to support those claims. The industry uses the FDA, USDA, and EPA. The major problem with this is the internal arguments within each department and the policies that follow. The basis for which these government entities are making policy are based more on politics than science. The FDA relies on industry provided information without independent long term peer

review. It approved GE foods as "substantially equivalent" without the long term studies to prove that claim. Requires no labeling. These are major concerns not only from private sector scientists, but from scientists within the FDA, USDA, and EPA departments. The policies Genetic Engineering developed through politics rather than sound science. Scientist on both sides of this issue believe government sponsored research should be free of politics and fair to both industry and consumer. Ultimately, not giving the choice for GE or Non GE foods is a disservice to both industry and consumer.

The GE products that are listed below have been altered through trangenics and approved by the FDA, and cleared by the EPA.
Currently in our food supply are ingredients from four GE crops. Corn, soy, canola, and cotton.

- Corn: corn flour, corn oil, corn meal, corn starch, corn gluten, and corn syrup. Sweeteners such as fructose, dextrose, and glucose.
- Soy: Soybean oil, soy flour, soy protein, soy lecithin, and soy is flavones.
- Canola: canola oil
- Cotton: cottonseed oil
- Hawaiian Papayas

The type and amount of transgenic material in the foods listed above could not be found by this subcommittee.

This subcommittee on Health, Social/Ethical, and Religion has reached the following conclusions concerning Lake County Crops and the use of transgenic modification.

- Currently there are no transgenic or Bt crops commercially grown in Lake County. Should they be allowed to be grown in Lake County the public should have the right to know. Transparency would increase pubic trust.
- The Lake County Board of Supervisors write a letter to the FDA requesting the need for labeling of transgenic foods for the health and safety reasons stated above.
- The subcommittee was split on allowing transgenic crops to be grown in Lake County. Two for a moratorium, two for allowing. The compromise is stated above.

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Chapter 7: Religious Issues

(Subcommittee Four: Melissa Fulton, Larry Heine, Sequoia Lyn-Franklin, Michelle Scully)

by Michelle Scully

Many of the world's religions have taken up the discussion of genetically modified food crops and have given theological perspective to it. Much of the perspective is based upon what is seen as the sacredness and intrinsic value of creation and the creatures within our world. Many religions state that genetic engineering defies the "Moral Order" of things by man-made manipulation by creating new entities that wouldn't have occurred in nature and which potentially cross species lines and put into question morally significant distinctions between humans and other animals. This is often referred to as "playing God" as in other ethical and theological issues such as stem cell research and abortion[1]. The Ecumenical Consultative Working Group on Genetic Engineering in Agriculture wrote a document calling upon Christians to give consideration to genetic engineering as an important ethical issue.[2] Locally, the Big Valley Pomo Indian tribe has drafted a letter stating their objection to genetically engineered plants stating their belief that genetically modified organism production in Lake County would alter or harm native plants they use in cultural heritage ceremonies (see Appendix 11)

Trans-species gene transfers offend some religions' dietary prohibitions and preferences.[3] Conversely, Rabbi Avram Reisner, who regularly addresses potential clashes with technologies with Conservative and Orthodox Jewish law has contended that genetically modified food can also be kosher and that the Jewish community may be willing to accept such technological changes[4]. Some of the theological questions posed are: What are the costs of this technology to the poorest? Does genetically modified food hold the solution to hunger and malnutrition in the world? Do the potential benefits of genetically modified products outweigh concerns? Is it right to patent and own genetically engineered life forms?[5]

The Vatican of the Catholic Church has hosted conferences on genetically modified organisms in order to discuss how to address the complex issue of world hunger and malnutrition with/or without genetically modified crops[6]. The World Hunger Programme of the United Nations states that hunger and malnutrition are the number one risk to health worldwide – greater than AIDS, malaria, and tuberculosis combined. The record number of hungry in the world is estimated to reach one billion soon[7]. The most highly cited statistic regarding hunger is that of the United nations Food and Agriculture Organization (FAO) which estimates that 963 million people worldwide are undernourished, up from 854 in 2006 (7). Bread for the World is a Christian organization formed for the purpose of creating a collective Christian voice to urge political and policy decision makers to end hunger at home and abroad. Their website states "scarcity of food is rarely the cause of hunger. There is more than enough food to feed everyone in the United States. The supermarket store shelves are stocked to the ceiling. But none of this matters if families have no money in their pockets. Poverty spoils every meal"[8]. Their 2009 annual hunger report entitled "Global Development: Charting a New Course" states that the 21st century world is experiencing a hunger challenge greater than any in the last fifty years. The factors they list are many, but include more recent challenges such as steep rises in food and fuel prices and the global financial crisis.

In 2004 the Vatican hosted the conference "Feeding a Hungry world: The Moral Imperative of Biotechnology" addressed many of the complex issues of poverty and hunger, a major concern for the Vatican[9]. Transgenic crops are suggested as a tool toward the alleviation of hunger by the potential to decrease the amount of land needed for cultivation, better soil conservation, and

allowing local people to have more reliable control over their food supply with less use of pesticides[10]. Among the many who have spoken out on the subject of GMOs is the Pontifical Academy of Sciences, which has argued that intellectual property rights of corporations, which allow patenting of GMO products "should not inhibit wide access to beneficial applications of scientific knowledge"[11]. The Academy has also called for closer study of ways to facilitate cooperation between the public and private sectors in the development of modern genetic technologies that can help promote solidarity and justice between the industrialized and developing worlds.

In the first 2009 issue of the Vatican newspaper, Cardinal Renato Martino, previously thought an avid proponent of genetically modified organisms (GMOs) spoke out on GMOs and profit and the correlation with famine and hunger worldwide in a discussion about issues that attracted the attention of the Vatican in 2008. In this interview he stated "the scandal of hunger in the world continues to be of concern; and the responsibility for the food crisis "is in the hands of unscrupulous people who focus only on profit and certainly not on the well-being of all people," said Cardinal Martino. If one wants to pursue GMOs (genetically modified organisms) one can freely do so, but without hiding that it's a way to make more profits," he said. Utilizing genetically modified foods calls for "prudence" because genetically modifying organisms can increase yields in some instances, he said, but people must not abuse their power to be able to manipulate nature.[12] The Vatican Counsel II stated that they acknowledge the just role of profit in the operations of businesses (agriculture and industry), but adds that 'the ultimate and fundamental goal of this development ….is to serve man…every man…"[13]

Reverend Roland Lesseps, an instructor at the Kasisi Agricultural Training Centre, a Jesuit program in Luska, Zambia presented a statement paper entitled "Church's Social Teaching and Ethics" at the international symposium "Genetically Modified Organisms: Threat or Hope?"[14] hosted by the Pontifical Council for Justice and Peace. His statement that "genetic modification does not meet the tests of the social teaching of the church for genuine integral development that respects human rights and the order or creation" provides an apt summary for many religion's theological perspectives on this issue. He quotes the Catholic Church's Social Teaching Perspectives (CST) by stating that within the CST is an inherent respect for human rights which makes clear that the economy is for the human person, the human person is not for the economy and that any economic intervention must be evaluated in terms of its impact on the well being of human persons in community.

In 1998 attorney Stephen Drucker, founder of the Alliance for Bio-Integrity filed a lawsuit against the Food and Drug Administration on behalf of seventeen plaintiffs, Christian, Jewish, Hindu, and Buddhist, brought the suit based upon their "objection to consuming genetically engineered food on the basis of religious principle."[15]. The suit states that the lack of labeling of genetically engineered foods is deleterious for religious people to observe their dietary customs. In the suit they demand mandatory safety testing and labeling of genetically engineered foods. Dr. Joseph Regenstein, professor of food science at Cornell University, consultant on Kashrut and Halal food preparation, and Director of the Cornell University Kosher and Halal Food Initiative says that the issue of 'biofoods' "is not a problem" for kosher certification.[16]

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Chapter 8: Social and Ethical Issues

(Subcommittee Four: Melissa Fulton, Larry Heine, Sequoia Lyn-Franklin, Michelle Scully)

by Michelle Scully

Biotechnology of food crops generates heated debate within the public and private sector. The topics of contention are myriad within this debate, not the least of which include the vast realms of social and ethical values regarding genetic engineering (GE). While these technologies offer promise to revolutionize fields as diverse as medicine to agriculture, many consumer advocates and countries also view them with unease and skepticism. There are a multitude of issues embroiled in the ethical and social discussion of GE crops. Somewhat discouragingly, debate even rages over the definition of benefits and risks. Social and ethical issues include (but are not limited to): concerns over possible effects to the ***environment*** (ex. pollen transfer from GE crops to non-GE plants; gene transfer between species; potential to increase sustainability of agriculture by decreased use of chemicals); ***food safety*** (ex. potential allergenicity to or toxicity of genetically modified foods; potential for removing allergenic components of foods; consumer anger over lack of labeling of GE foods; potential long-term effects of consuming GE foods), ***hunger*** (ex. possible tools for farmers in developing countries; distribution issues and complexity of issues in global hunger; nutritional enhancement of crops to combat malnutrition in developing countries), ***regulation*** (ex. seed integrity; distrust of governmental regulation; distrust of academia due to perceived/actual conflicts of interest of funding sources;) and ***personal values*** (ex. anti- or pro- technology biases; misinformation on both sides of the issue; biased and/or difficult to discern information; intrinsic personal or religious beliefs) (1,2,3,4,5). Please see Chapter 6 for health and food safety discussion.

There are two primary areas of discussion within this continuum of discussion about GE crops: scientific and ethical (1,2,3,4,5). While science is traditionally concerned with causal (a decisive factor or influence) relationships, ethics is in turn concerned with what we think we should do or what would be 'right'. To apply ethics to address a problem is to look for justification or reasoned assessment for the actions---the principles behind why we should or should not undertake a course of action or seek to affect an outcome. Conclusions that are *ethically justifiable* center around two very different constructs. The first construct is the *empirical*, or factual assertions based upon how the world is, and what can be proven based upon the best scientific principles, theories, and observations. The second are *value-laden assertions,* those that are formulated around how people feel things should be (1). Value-laden assertions are evaluated based upon the best available ethical judgments, principles and theories. *Applied ethics* is the process of identifying and analyzing arguments for various conclusions and then determining whether the arguments are sound. A sound argument is defined as one in which all the premises are true and one in which no mistakes in reasoning have been made (1).

In an age of lightning fast access to information via the Internet, information as well as misinformation can be disseminated in an immediate and often emotive manner that former information technology lacked. Social dialogues are often held via the Internet and opinions formed and reformed in an ever increasing global format as information dissemination isn't restricted by the constraints of proximity and time as was true of earlier times (2). To paraphrase Dr. Sheila Jasanoff, Pforzheimer Professor of Science and Technology Studies at the John F. Kennedy School of Government at Harvard University … states "*...the good news is that people are talking about these issues... the bad is that we are not necessarily always talking about the same things*" (Pew 2, p. 14). One of the recurring statements that resonated with this

subcommittee while researching the social and ethical issues of genetic engineering is the repeated request of the public to be "educated" on this complex topic (2, 3). Lack of knowledge or information about genetic engineering of food crops is a common concern for both the public and scientific sector.

In discussing any complex issue it is helpful to be clear about the terminology, procedures, or methods. Much about this subject is daunting and confusing to the layperson. The terms *biotechnology*, *genetically modified*, *genetically engineered*, and *transgenic* are often used interchangeably making the discussion that much more difficult. Our subcommittee recognized this desire for understanding and attempted to contribute to that request by providing a brief outline of commonly used terms along with reference sources for further inquiry (see Glossary).

The field of biotechnology is fairly young. Commercial biotechnology began in 1973 with the discovery of the recombinant deoxyribonucleic acid (rDNA) technique. This technique allowed foreign genes to be inserted into microorganisms and to pass to other organisms through cell division. This technique was patented by Stanford University and earned over $200 million dollars in royalties over a twenty-two year period. Human insulin was the first pharmaceutical rDNA product, created by the biotechnological company Genentech (6). After the advent of rDNA technology, the next major biotechnological breakthrough was the development of hybridoma technology (7). Hybridomas produce multiple antibodies, which allowed the production of monoclonal antibodies (Mab). Monoclonal antibodies have been the foundation of tremendous drug development for humans. Polymerase chain reaction (PCR) technology came next in the history of biotechnological advancements. PCR provides such a quick and easy method for generating unlimited copies of any fragment of DNA that it is sometimes referred to as "molecular photocopying" (8). It allows any specific piece of DNA to be characterized and analyzed, even very complex mixtures from body fluids, microorganisms, plants, and animals even thousands of years old or older. It is often used in criminal forensics. "PCR is the most important new scientific technology to come along in the last hundred years," says Mark R. Hughes, deputy director of the National Center for Human Genome Research at the National Institutes of Health (better known as the Human Genome Project) (8).

In the 1980's and 1990's gene transfer techniques that allowed the transfer of DNA not only to microorganisms but to plants and animals as well were discovered and genetic engineering expanded to become an increasingly sophisticated field (3). With this expansion came increased controversy and the new field of bioethics (1,2,3,4,5,10). These examples of biotechnology were given to give the layperson a basic background in the field and the products that have come from the technology as well as some foundation for the discussion of research and development, intellectual property, and patents. Genetic engineering in this discussion of social and ethical issues in the scope of this Genetic Engineering Advisory Subcommittee will be limited to food crops, and not to pharmaceuticals or human applications (ex. gene therapy).

Ethical analysis applied to the subject of genetically engineered crops should provide answers to questions we all have such as: Should we genetically engineer foods to produce, for example, health- and nutrition-enhancing traits? How so or how not? Are we ethically justified in doing this? How do we approach the impact of biotechnology in our country? In developing countries? How do we determine what is ethical? Who gets to say so? What about choice? Food choice is very important to people and it also runs the gamut from those desirous of eating only a certain type of food to those who value low-cost and accessibility (1, 2, 3, 5, 9). The acronym "GMO" is commonly used in discussions of genetic engineering. A genetically modified organism (GMO) is a product specifically developed through genetic engineering and a genetically modified crop is a plant product specifically developed through genetic engineering (See Glossary). In this discussion, every effort has been made to use the term genetically

engineered (GE) in place of GMO. There are three main categories of genetically modified crops either currently in use or under research and development (4). They are:

- Enhanced input traits such as herbicide tolerance (HT), insect and virus protection, environmental tolerance (ex. drought, salinity, cold).
- Value-added output traits such as higher amino acid content and omega-3 fatty acids.
- Crops that produce pharmaceuticals ("pharming") to create therapeutic proteins, vaccine production, biofuels.

The public has expressed concerns about the nature of the research system of these technologies and the potential for corporate monopolization of these techniques. In 1998 the University of California Berkeley's (UCB) Department of Plant and Microbial Biology received $25 million dollars over five years from Novartis/Syngenta in what was called "research-support" for funding in plant genetics (12, 13, 14). There were also accusations that it affected the tenure review a faculty member who was critical of the agreement (11, 12, 13, 14). At the time the deal was heralded as 'path breaking' venture that would increase research funding, access to specialized equipment, and additional research opportunities (11, 12, 13, 14). Between 1995 and 2000 private funding at University of California Berkeley increased by 77%. In 2003 – 2004 the University received $93.2 million from industry agreements. In 2005, they were awarded 424 patents, making UCB a national leader among universities for patent awards (11) Patents are now a significant source of income for universities, particularly in the field of molecular biology. UCB was the subject of furious public outcry and the University found that this arrangement had done serious damage to their reputation as one of the premier research institutions (13). A professor who had served on the Academic Senate when the arrangement was made said that he agreed with a Michigan State University peer review report recommendation that suggested UCB "review its arrangements with industry to ensure that those ties did not compromise researchers' ability to be seen as honest brokers of information and analysis on important issues (14). One of the peer reviewers said that recommendation, like others in the report, applies to all public universities as well. The deal created the impression that the department was "on the dole" and "biased toward the funding source," he said. "Universities as institutions can only be objective observers on the scientific and regulatory scene to the extent that some distance remains between them and industry funding sources" (14).

What are some of the inherent problems in this system of research? The cost of research and development and the path from basic research to ultimate product development is a very long and costly one. Sometimes the scope of a patent must be broadly based in order to provide protection to cover a wide-range of products, some as of yet unseen but only imagined by the applicant for the patent (7). This dilemma is not new only to biotechnology, but is increasingly common in new fields where the technology moves incredibly quickly. DNA patenting is a very complex arena and society has very polarized views as to whether it should be allowed at all (1, 3, 5, 7, 8). On the other side, these businesses are very dependent on the protection of intellectual property (IP) due to the enormous sums of money they have invested in research and development. Many, many products never make it to the final development stages, yet the development costs are incurred all the same (7). Public funding for research is often limited or not available at all. Thompson notes that in *Biotechnology's Bitter Harvest* the authors argue that agricultural universities have an ethical commitment to serve farmers and that they were turning toward developing technologies that would benefit agribusinesses instead (5, 15).

Facing public distrust is challenging, but it is important that these charges be addressed to restore public trust in these venerable research institutions. Scientists employed by public and private

institutions must always be stringent in maintaining their objectivity and as transparent as possible as these concerns are particularly important to the public when they are receiving industry funding (2, 12, 13, 14). In the United Kingdom the Nuffield Council on Bioethics (3) suggests

> To mitigate the potentially negative effects of monopolies on key plant technologies we recommend that public sector institutions which hold such patents serve the wider public interest by retaining their intellectual property and licensing it in a fair and equitable manner so that key technologies are not tied up in exclusive and inaccessible license deals (p. 60, Sec. 3.47).

Some people find it inherently disturbing (sometimes called the "yuck factor" or the "wisdom of repugnance") to think of genes and the genome as "malleable" or subject to manipulation as well as disagreeable that those same methods can be patented and then restricted in their application in the hands of only a few companies (2, 6, 11, 16). Jasanoff addresses the these issues and points out that, while respective of individuals' feelings,

> The issue is not whether or not we should listen to our 'yuck' intuitions, but that in institutions where reasoned argument is the norm, it is not acceptable to invoke the 'yuck factor' to justify a decision. We cannot be guided by individual, subjective statements about what is disgusting. The danger of operating according to some feeling of disgust is that it can be used to justify discriminatory, marginalizing, and stigmatizing decisions. In short, in this country it is seen as dangerous to not be able to have a reasoned explanation for your beliefs (2, p. 17).

Some object to genetic engineering on a personal belief that it is unnatural and violates "Natural Laws" (5, 5, 17, 19). For a discussion of religious perspectives on genetic engineering, please refer to Chapter 7. Some prescribe to "telos" (5, 17). "Telos" is derived from teleology, which is defined as "a philosophy of nature that seeks to explain biological processes in terms of function, purpose, and design (18). Thompson writes:

> Although teleology does not necessarily prescribe particular ethical norms, versions of teleology that find a predetermined design in nature, often the work of a supernatural intelligence, move quickly to the ethical judgement that humans deviate from the preordained purposes of this plan at their physical and spiritual peril (5).

Even within our small subcommittee it has been illuminating to examine our own various thoughts and belief systems. From a personal perspective, a member of this subcommittee writes [sic]

> "In the Complex issue of Ethics, there are many who believe and agree that crossing the species barrier and using the DNA of virus' (viral promoters) to produce a GE product is simply against the millions of years of Nature's Laws. There are Natural laws which guide and govern the Planet and to mess with these Natural Laws invites and evokes disaster on the level of the Natural Order. Naturalists and Spiritualists agree in being stewards of the land, NOT in manipulating and sundering dominance over Nature. Working sustainably and in Balance with Nature is the alignment and definition of Ethics according to those who value the heritage that we as the people are responsible for taking care of. This is why the Public-AT-Large is concerned about the Science Sector. When we put 'concerns' in this report it would only deem respectful to articulate WHY people of the public sector have these concerns. Nature has a proven track record of millions of years of Her own genetic wisdom. To think we know MORE than the Greater Intelligence residing in Nature Herself is found to be arrogant" (20).

Ethics and regulation butt up against each other in the discussion of GE. Ethics can be seen as "questions, not answers" and regulation as "answers, not questions" (2). The social challenge is in how can that inherent tension between the two be reconciled. There are differences in the models applied to address these issues and they vary in application between countries and between people. Some believe that risk assessments should be value-laden while others do not (Pew ref). It has been suggested that what is a central issue between critics and advocates of biotechnology may not really be a question of ethics, but a disagreement over harm and how it's assessed (5). Two major viewpoints exist, one that has been called "mainstream" and the other "precautionary" (5, 21, 22, 23, 24, 25, 26, 27). The "precautionary principle" originated in Germany and is widely used there (26, 27). The United Nations Conference on Environment and Development met June 14, 1992 and in the Rio Declaration put forward twenty-seven environmental "precautionary principles" in part of a "precautionary approach" to be included as part of the United Nations Environment program (28). Its use was adopted in the Maastricht Treaty of the European Union (EU) (27, 29). In 1998 the "Wingspread Conference on the Precautionary Principle" issued a statement calling for "governments, corporations, communities, and scientists to implement the precautionary principle which exhorted taking anticipatory action in the absence of scientific certainty, or in other words, even if not all cause and effect relationships are understood (30). The Wingspread Statement states that "substantial unintended consequences" have been brought about by industrial society. Several environmental action groups have adopted it, the most notable being Greenpeace (27). Advocates of a precautionary principle believe it injects values into regulation and that it is a "revolutionary" tool for environmental advocacy (31, 32).

Proponents of a precautionary principle are often at odds with scientific risk assessment or "uncertainty" (27, 31). One of the primary areas of division is in assessment of risk or harm. In van den Belt's review of the precautionary principle he proposes that the standard of "no-risk" is too high for any technology to meet and that there is no agreed upon consensus definition, agreed upon guidelines, or criteria for it's application (26, 27, 33). Ragnar and others describe three main areas of concern: legally ill defined; conflict with scientific risk analysis; and international trade issues (27, 33, 34, 35, 36). Fault for accidental or purposeful lack of clarity in trade issues is evenly divided. Many authors accuse industry *and* environmentalists of misusing both risk assessment and a precautionary principle approach as a means of imposing trade sanctions without the benefit of prior negotiations (25, 27, 33, 38). Another concern is the disparity of the application of the precautionary principle in the EU and that reflection in recent court rulings (33, 34). Some say the precautionary principle focuses only on the risks associated with technology and not the benefits that may result from it (26, 34, 35). Dr. Henry Miller's statement is illustrative of that concern:

> The precise term of art 'precautionary principle' is not used in U.S. public policy, but the regulation of such products as pharmaceuticals, food additives, gene-spliced plants and microorganisms, synthetic pesticides, and other chemicals is without question "precautionary" in nature. Surely greater precaution would be appropriate not to gene-splicing but to the cruder, less precise, less predictable 'conventional' forms of genetic modification. Furthermore, in spite of the assurance of the European Commission and other advocates of the precautionary principle, regulators of gene-spliced products seldom take into consideration the potential risk-reducing benefits of the technology (34, 35).

The European Commission (EC) proposed the development of a "GMO authorization process" to the European Food Safety Agency which stated the EC will introduce "additional proportionate risk management measures on a case by case basis . . . if specific risks are identified, and reinforce consensus in the authorization process" (39). Other authors suggest to that risk analysis and a precautionary approach are not antithetical to one another in developing policy

(37, 40, 41).

What form of regulatory tool should be used and who should be responsible for its final implementation? The EU's Communication on the precautionary principle attempted to reconcile these problems in approach asserting that risk assessment should be part of a precautionary principle.

> A scientific evaluation on the potential of adverse effects should be undertaken based on the available data when considering whether measures are necessary to protect the environment, the human, animal or plant health. An assessment of risk should be considered where feasible when deciding whether or not to invoke the precautionary principle. However it is not possible in all cases to complete a comprehensive assessment of risk, but all effort should be made to evaluate the available scientific information…. Measures based on the precautionary principle must not aim at zero risk, something which rarely exists (39).

The challenge regulators and countries face is to create balanced scenarios between what seems like competing risk scenarios to address these issues.

Ethics discussions of genetic engineering enable broader discussions of what's going on in our community and hopefully, may eventually influence policy discussions. Dr. Stefan Sperling, Harvard colleague of Dr. Sheila Jasanoff asks, "How do you engage different cultures and different perspectives in such a way as to not just affirm your own ways of seeing? One way is to learn to listen—not only to people who are like us, but those who are very different" (2). Dr. Paul Thompson welcomes the discussion and suggests that the attention is guaranteed to thrust the technology into conversations both "prudent and moral" on the many sides of the issue (2, 42, 43). He eloquently offers, "Failure to acknowledge the full range of ethical perspectives can create the impression that one is promoting a utilitarian trade-off approach to ethical decision making. This impression does not serve the goal of a fair and open hearing for all ethically motivated points of view".

It was the intent of this subcommittee to provide a very brief overview of very complex topics. In no way can the brevity of this report replace the comprehensive references available on the subject (1, 2, 5, 6). Our goal was to recognize the great range of value judgments, ethical concerns, and responsibilities involved in the societal and ethical debate of genetically engineered crops. We recognize there are issues of great import here and that as a county and country that we apply ourselves diligently to ensuring that such technology is approached with careful thought to both potential harm and benefit and with due diligence, adequate and transparent research, analysis and assessment.

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42) Thompson, Paul B. Should We Have GM Crops? 5 Santa Clara Journal of International Law 2 (2007). http://www.scu.edu/scjil/archive/v4_ThompsonArticle.shtml

Subcommittee recommendations: Here in Lake County we offer the following findings which were arrived at in good faith and open-mindedness and fairness to all in an authentic desire in delving into the contentious issues of genetic engineering, with the intention to arrive at an end point for the betterment of the county of Lake as a whole and in an effort to create unity.

Recommendation 1: We are in agreement about the potential of biotechnology and genetic engineering to address specific issues such as disease resistance, drought and salinity tolerance, etc. We support companies investing in new non-GE technology like marker assisted selection (MAS) which involves analyzing plants for genetic markers associated with desirable traits, then using conventional breeding methods to introduce the genes for those traits into a host.

Recommendation 2: Sadly, the public trust in private and public research institutions has been degraded by contributions to research by industrial agricultural biotechnology companies. We recommend that the institutions recognize that any apparent conflict of interest may create doubt as to the integrity of the research generated from those institutions and how important these institutions are to our society. It is vitally important to the public that they have confidence in the research that our pubic and private institutions conduct and vital to those institutions that they maintain that trust with transparency, accountability, funding, and reporting.

We recommend that our local and national governments recognize the value of public investment in such research so that the results can be placed in the public domain if ever possible. We recommend that the Lake County Board of Supervisors utilize widely accepted independent *peer reviewed* information regarding any genetically engineered crop that may be grown in Lake County, to consider research beyond 'substantial equivalence' and that all aspects of the effects of such genetically engineered crop be considered.

Recommendation 3: In recognition of the vital role that farmers play and consumers rely on through the farming community and to farmers who contribute vitally to the health of our community, we must maintain, and sustain this agricultural heritage, and we request that due consideration must be given to all involved, conventional and organic farmers. To deny the use of technology, including genetic engineering, as a tool, would be a denial of resources and the potential of resourcefulness. We believe in such tools for farmers such as in for disease resistance and drought tolerance and are aware of the bad examples of genetic engineering, but desire not to diminish the possibilities of family farms by focusing only on the bad and denying the potential for good.

We wish to empower the family farmer, to empower the small business community, to support a greater return of their investment to the family farmer and reasonable prices for the goods that they produce. We recognize the value of healthful agricultural products. We support a buy

local, buy California, buy United States products to support the farmers who contribute to our economy by their efforts. Lake County farmers contributed $61.595 million dollars in fruit and nut crops, $2.658 million in livestock and poultry production, $235,500 in vegetable crops in gross revenue to our community in 2007.

Support our Lake County, California, and national family farmers. Read labels, buy California or United States as country of origin. Support our community, support our country. Strengthen our food safety system, maintain our food independence, reduce our carbon footprint. Support from the ground up!

Recommendation references:

USDA Ag Census: http://www.census.gov/prod/2007pubs/08abstract/agricult.pdf
Farm Policy Facts
http://www.ilovefarmers.org

Glossary

(White Paper subcommittee: Andre Ross (chair), Victoria Brandon, Steve Devoto, JoAnn Saccato, Michelle Scully)

Bacillus thuringiensis (Bt): a soil-dwelling bacterium that forms crystals of insecticidal endotoxins (Cry toxins) lethal to larval forms of certain species of insects (depending on the variety of Bt). Since it works by binding to the appropriate receptor on the surface of midgut epithelial cells, any organism that lacks the appropriate receptors in its gut cannot be affected. Bt has been used to control insect pests since the 1920s, primarily caterpillars but also including other types such as mosquito larvae. Because of their specificity, these pesticides are widely regarded as environmentally friendly, with little or no effect on humans, wildlife, pollinators, and most other beneficial insects. Some plants have been genetically engineered to express Bt in their tissues, thus generating their own pesticide. (5)

Bioballistics: gene gun or a biolistic particle delivery system, originally designed for plant transformation, used to inject cells with genetic information. The payload is an elemental particle of a heavy metal coated with plasmid DNA. (5)

Biotechnology (*bio* meaning life plus *technology* ("practical application of knowtedge") broadly includes the use of living organisms to create a new process or product as in the production of yogurt, wine, beer, bread, and cheese.

DNA (Deoxyribonucleic acid): a nucleic acid arranged in the form of a double helix, and containing the genetic instructions used in the development and functioning of all known living organisms and some viruses. The DNA segments that carry this genetic information are called genes. (5)

Genetic engineering (GE): a specific technique of genetic modification that enables the introduction of a gene(s) from one species into another (also called transgenlcs). The term initially meant any of a wide range of techniques for modifying or manipulating organisms through heredity and reproduction. End result, to put it simply, the genetically engineered form of a plant (for example) contains gene(s) from a source that is not the plant's parent .While there are a number of techniques for artificially moving genes, the oldest and most common is the use of recombinant deoxyribonucleic acid (rDNA) (3). Now it is more likely when the term is being used it is denoting the narrower field of recombinant-DNA technology. This technique uses a biological vector; a plasmid or viral chromosome into whose genome a fragment of foreign DNA is inserted, to introduce foreign DNA into a host cell in the cloning of DNA (4). Newer transgenic techniques are electro- and chemical poration, microinjection, and bioballistics (1). A genetically engineered crop is one that has been created or modified through genetic engineering. It does not include nonliving or non-reproducing organisms or products.

Genetic modification: changing the genetic traits of an organism by intentional modification, including both cross-breeding and genetic engineering.Within genetic modification there are numerous methods that can be used to alter the genetic composition a plant or animal, which is inclusive from traditional hybridization to the highly technical procedure called bioballistics (1,2).

Glyphosate (*N-(phosphonomethyl) glycine*): a broad-spectrum systemic herbicide used to kill weeds, and the most frequently used herbicide in the United States, absorbed through foliage and

translocated to growing points. Because of this mode of action, it is only effective on actively growing plants. Initially patented and sold by Monsanto Company in the 1970s under the trade name Roundup, its U.S. patent expired in 2000. It is also available in other formulations. Some crops have been genetically engineered to be resistant to glyphosate (i.e. "Roundup Ready,") allowing its use against both broadleaf and grass weeds in the resistant crop. (5)

Hybridization: in plant breeding, this refers to deliberate crosses between populations, breeds or cultivars within a single species. Hybrids are commonly produced and selected because they have desirable characteristics not found or inconsistently present in the parent individuals or populations. The word "hybrid" also refers to naturally-occurring or assisted crosses between animals or plants of different (related) species or (much more rarely) different closely related genera, but does *not* include transgenic manipulation. (5)

Pesticide: "Any substance or mixture of substances that prevents, destroys, repels, or mitigates any pest, including insects, weeds, fungi, bacteria, viruses, mice and other animals." (6)

Traditional plant breeding includes three types:

- Natural cross-breeding, which occurs by natural breeding (i.e. via wind, insects, birds, water) and where survival of resulting individuals is determined by the environment through natural selection
- Open.pollination cross-breedlng in which plants also breed naturally, followed by deliberate selection of individuals by human agency
- Selective cross-breeding (more commonly known as artificial selection) in which plant varieties selected by humans are then crossed by artificial breeding (human intervention). It usually takes generations upon generations to see a change occurring by selective breeding. Hybridization is a form of selective cross-breeding.

Transgenics: see *genetic engineering*

Glossary References

1)http://www.Ucsusa.orglfood_and_agriCUltureiSCience _andJmpactsisciencelgeneticOengineerin g-techniques.html. Union of Concemed Scientists.
2) www.whybiotech.com
3) Lemaux, P. http://UCbiotech.Org/biotechJnfo/annuaueview/part_1/index.html
4) http://medical-dictionary.thefreedictionary.com/biOI09ical+vector
5) http:// en.wikipedia.org
6) Lemaux, Peggy G. (2008). Genetically engineered plants and foods: A scientist's analysis of the issues (part I). *Annual Review of Plant Biology* 59:771-812. http://arjournals.annualreviews.org

Appendices

Chapter 1: Overview and Regulatory Framework

Appendix 1 – Sample of Release Notification Letter and Permit 2009

U.S. DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
BIOTECHNOLOGY REGULATORY SERVICES

BRS NOTIFICATION - INTRODUCTION OF GENETICALLY ENGINEERED PLANTS

1. NAME, ADDRESS, TELEPHONE, AND EMAIL OF APPLICANT

Name: Lorrine Gray
Position:
Organization:
Organization Unique ID:
Address:

County/Province:
Town/State/Land:

Day Telephone:
FAX:
Alternate:

Email 1:
Email 2:

2. INTRODUCTION TYPE

- ☐ Importation
- ☐ Interstate Movement
- ☐ Interstate Movement and Release
- ☐ Release

3. APPLICANT REFERENCE NUMBER

4. CONFIDENTIAL BUSINESS INFORMATION VERIFICATION (CBI)

Does this application contain CBI? ☐ Yes ☒ No

CBI Justification:

N/A

5. REGULATED ARTICLE

Scientific Name:

Common Name:

Cultivar and/or Breeding Line:

6. PHENOTYPIC DESIGNATION

7. INTRODUCTION

8. ADDITIONAL INFORMATION

None

I, Lorrine Gray, 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.

I acknowledge this is not an application to move or import select agents, the genes expressing select agents, or the toxins made by the select agents, as described in 9 CFR 121.

If there are any changes to the information disclosed in this application, I will contact APHIS.

9. SIGNATURE OF RESPONSIBLE PERSON	10. DATE

Appendix 1 – Sample of Release Notification Letter and Permit 2009 (continued)

The collection of this information is authorized by the Plant Protection Act of 2000. The information will be used to determine eligibility to receive all types of permits. No permit will be issued until this application has been approved.

U.S. DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
BIOTECHNOLOGY REGULATORY SERVICE

APPLICATIONS FOR PERMIT OR COURTESY PERMIT UNDER 7 CFR 340

(Genetically Engineered Organisms or Products)

1. NAME, ADDRESS, TELEPHONE, AND EMAIL OF APPLICANT

Name: [illegible]
Position:
Organization:
Organization Unique ID:
Address:

County/Province:
Township/Island:

Day Telephone:
FAX:
Alternate:

Email 1: [illegible]
Email 2:

2. INTRODUCTION TYPE

☐ Importation
☒ Interstate Movement
☐ Interstate Movement and Release
☐ Release

3. PERMIT TYPE

☒ Standard Permit
☐ Courtesy Permit

4. PURPOSE OF PERMIT

☐ Industrial Product
☐ Pharmaceutical Product
☐ Phytoremediation
☒ Traditional

5. CONFIDENTIAL BUSINESS INFORMATION VERIFICATION (CBI)

Does this application contain CBI? ☐ Yes ☒ No
CBI Justification:
N/A

6. REQUEST TYPE

☒ New ☐ Amendment ☐ Renewal ☐ Variance ☐ Amendment, Renewal and/or Variance

Amendment/Renewal Description:
Previous Permit Number(s):

7. MEANS OF MOVEMENT

[illegible]

8. VARIANCE VERIFICATION

Have you previously applied for variance(s) that you wish to apply to this permit? ☐ Yes ☒ No
Variance Number(s):

If so, describe in a brief summary how the variance will be applied:
N/A

9. REGULATED ARTICLE

Scientific Name:

Common Name:

Any biological material (e.g., culture medium, or host material) accompanying the regulated Article during movement:
Country and locality where the donor organism, recipient organism, and vector or vector agent were collected, developed, and produced:

Processes, Procedures, and Safeguards Description:

10. ARTICLE SUPPLIER AND/OR DEVELOPER

11. PHENOTYPES/GENOTYPE

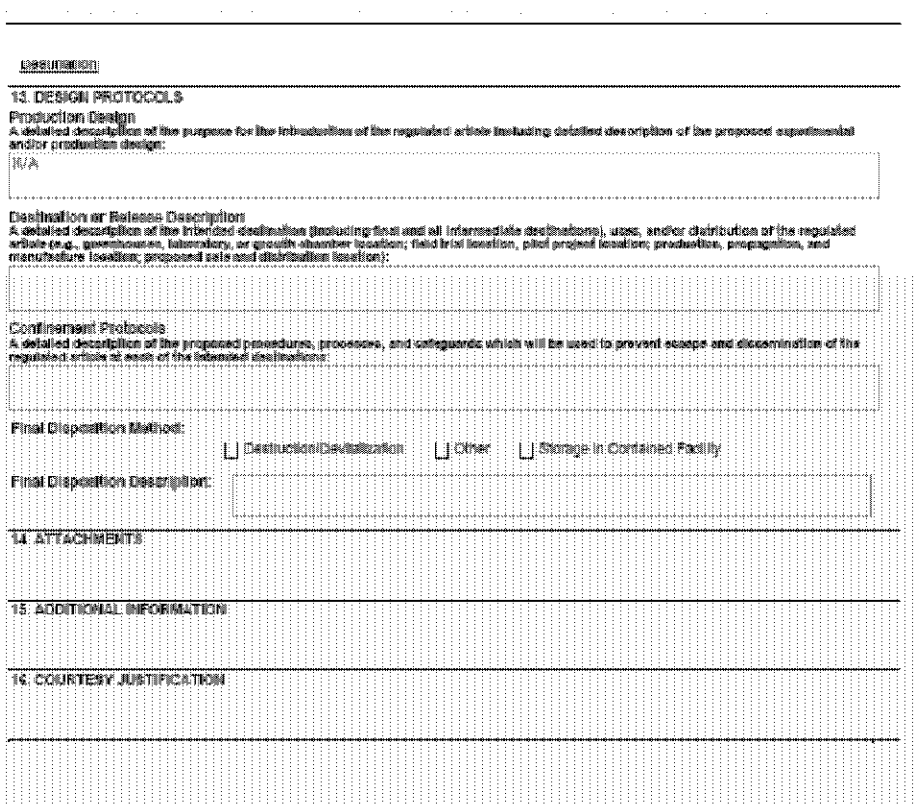
12. INTRODUCTION

Point of Origin:

[illegible]

Page 1 of [illegible]

Appendix 1 – Sample of Release Notification Letter and Permit 2009 (continued)



Destination

13. DESIGN PROTOCOLS

Production Design
A detailed description of the purpose for the introduction of the regulated article including detailed description of the proposed experimental and/or production design:

N/A

Destination or Release Description
A detailed description of the intended destination (including first and all intermediate destinations), uses, and/or distribution of the regulated article (e.g., greenhouse, laboratory, or growth chamber location; field trial location, pilot project location; production, propagation, and manufacture location; proposed sale and distribution location):

Containment Protocols
A detailed description of the proposed procedures, processes, and safeguards which will be used to prevent escape and dissemination of the regulated article at each of the intended destinations:

Final Disposition Method:

☐ Destruction/Devitalization ☐ Other ☐ Storage in Contained Facility

Final Disposition Description:

14. ATTACHMENTS

15. ADDITIONAL INFORMATION

16. COURTESY JUSTIFICATION

WARNING: Any use of artificial or man-materially false, fictitious, or fraudulent statements or representations is subject to civil penalties of up to $250,000 (7 U.S.C. § 7734(b)) or imprisonment of not more than 5 years, or both (18 U.S.C. §1001).

Page 2 of 3

I, Connie Gray, hereby certify that the information in this application and all attachments is complete and accurate to the best of my knowledge and belief.

I acknowledge this is not an application to move or import select agents, the genes expressing select agents, or the toxins made by the select agents, as described in 9 CFR 121.

I will not introduce the regulated articles described in this application until APHIS has deemed the application complete and has granted the permit. By signing this permit, I agree to comply with any and all state, local, and tribal laws and regulations that may apply to the introduction of the articles described in this application.

If there are any changes to the information disclosed in this application, I will contact APHIS.

17. SIGNATURE OF RESPONSIBLE PERSON	18. DATE

WARNING: Any use of artificial or man-materially false, fictitious, or fraudulent statements or representations is subject to civil penalties of up to $250,000 (7 U.S.C. § 7734(b)) or imprisonment of not more than 5 years, or both (18 U.S.C. §1001).

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Appendix 2– California GE Research on Lake County Commercial Crops (Marc Hooper)

Current California GE Research on Lake County Food Crops

Food Crops Grown in Lake County Crops[1]	Total Acres	Organic	Crops Deregulated by USDA Commercialized or Not[5] 6/2/1992 thru 3/26/2009 (17 yrs)		
References >			www.nbiap.vt.edu		
			Pending	Withdrawn	Approved
Fruit & Nut Crops					
Pears	2,208	33			
Walnuts	2,702	1,709			
Misc. Fruit & Nuts[2]	70	3			
Wine Grapes	8,345	126			
Total Acres	13,325	1,870			
Vegetables					
Vegetables[3]	50				
Chicory				1	1
Melon				1	
Potato				3	5
Squash					2
Tomato				2	11
Total Acres	50	17			
Nursery					
Nursery - Greenhouse (sq. ft.)	69,900				
Nursery - Field	77				
Total Acres	79	10			
Timber					
Timber Yield (Board Feet: MBF[2])	3,684				
Total Board Feet (MBF[2])					
Field and Seed Crops					
Irrigated Pasture	1,800				
Range	90,000				
Miscellaneous[4]	2,100				
Alfalfa			1		1
Corn (Field and Sweet Corn)			4	7	20
Rice					2
Wheat				3	
Total Value	$ 68,766,520				

[1] Crops, acreages and values based the Ag Commission's 2007 Lake County Crop Report

[2] Includes apples, peaches, strawberries, melons, dried fruits, olives, etc.

[3] Includes beans, peas, tomatoes, squash, pumpkins, etc.

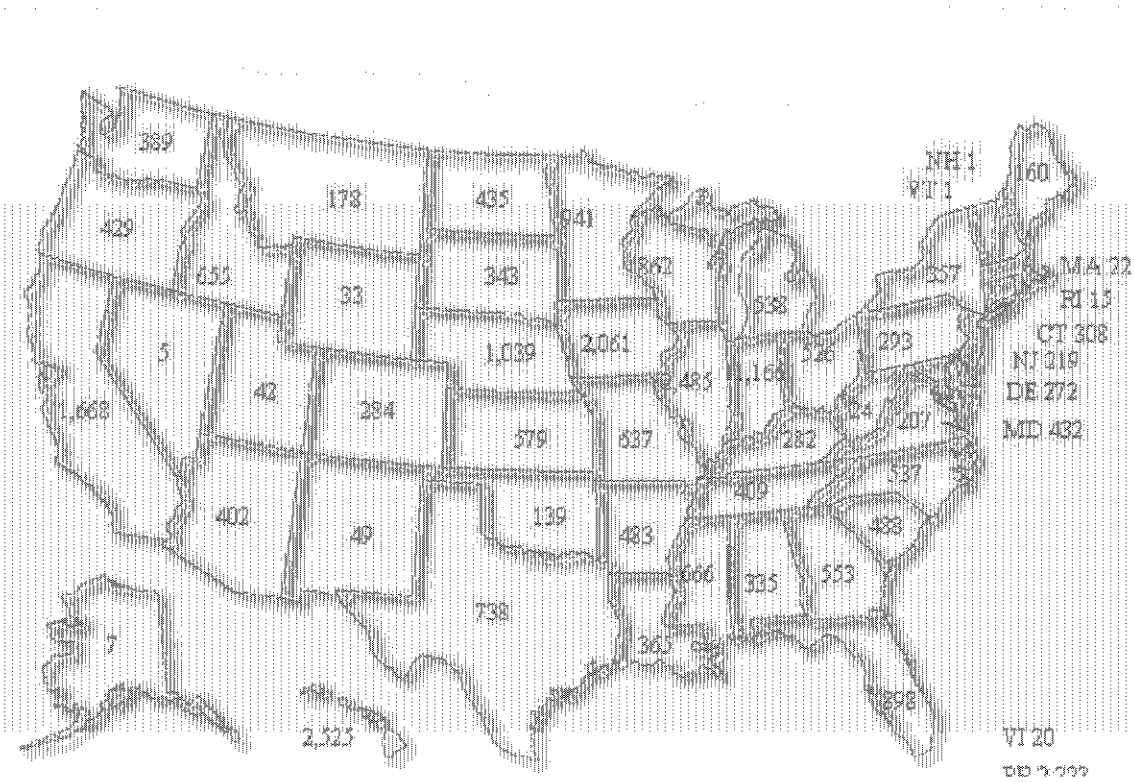
[4] Includes Wild rice, oat hay, alfalfa, grass hay.

[5] Source of information - Web query at: > http://www.nbiap.vt.edu/cfdocs/biopetition3.cfm for date range shown at top. Permit action: Pending, Withdraw, Approve.

[6] Field Test Release Applications in the US, APHIS Database – through 3/30/2009: Notifications 13,935 records; Full Release Permits Only 1,563 records.

Appendix 3—Number of Field Tests by State in the U.S (Marc Hooper)

(To March 30, 2009)



Reference: Information Systems for Biotechnology
http:://www.isb.vt.edu.cfdocs/biocharts1.cfm

Appendix 4, GAO Highlights (Steve Devoto)

GAO
Accountability Integrity Reliability

Highlights

Highlights of GAO-09-60, a report to the Committee on Agriculture, Nutrition, and Forestry, U.S. Senate

Why GAO Did This Study

Genetically engineered (GE) crops—including crops engineered to resist pests or tolerate herbicides—are widespread in the United States and around the world. Taking direction from the 1986 *Coordinated Framework for Regulation of Biotechnology*, the U.S. Department of Agriculture (USDA), Environmental Protection Agency (EPA), and Food and Drug Administration (FDA) regulate GE crops to ensure that they are safe. The unauthorized mixing of some GE crops with non-GE crops has caused controversy and financial harm. GAO examined (1) unauthorized releases of GE crops, (2) coordination among the three agencies, and (3) additional actions they have proposed to improve oversight. GAO gathered data from agencies and stakeholders, used criteria from prior GAO work to assess coordination, and reviewed agency proposals.

What GAO Recommends

GAO recommends that (1) FDA make public the results of its early food safety assessments of GE crops; (2) USDA and FDA develop an agreement to share information on GE crops with traits that, if released into the food or feed supply, could cause health concerns; and (3) USDA, EPA, and FDA develop a risk-based strategy for monitoring the widespread use of marketed GE crops. FDA agreed with the first recommendation, and, with USDA, agreed in part with the second. The agencies agreed in part with the third recommendation. We stand by the recommendations.

To view the full product, including the scope and methodology, click on GAO-09-60. For more information, contact Lisa Shames at (202) 512-3841, or shamesl@gao.gov.

November 2008

GENETICALLY ENGINEERED CROPS

Agencies Are Proposing Changes to Improve Oversight, but Could Take Additional Steps to Enhance Coordination and Monitoring

What GAO Found

Unauthorized releases of GE crops into food, animal feed, or the environment beyond farm fields have occurred, and it is likely that such incidents will occur again. While there is no evidence that the six known releases into the food or feed supply or into crops meant for the food or feed supply affected human or animal health, some resulted in lost trade opportunities. Moreover, the total number of unauthorized releases into the environment is unknown. USDA and EPA have the authority to inspect fields in which GE crops are tested, but crop developers have detected most violations. USDA and EPA have taken enforcement actions in response to violations, ranging from warning letters to significant penalties. The agencies have used lessons learned from unauthorized releases to make regulatory and policy changes. For example, USDA increased inspections of field trial sites for GE crops producing pharmaceutical compounds; EPA discontinued a policy under which a GE crop containing a pesticidal agent could be approved for animal feed, but not for food; and FDA established a voluntary early food safety evaluation program for certain GE crops intended for food use to help mitigate the impact should unauthorized releases occur during field trials, although it has not made these evaluations available to the public.

USDA, EPA, and FDA routinely coordinate their oversight and regulation of GE crops in many respects, but could improve their efforts. Specifically, USDA and FDA do not have a formal method for sharing information that could enhance FDA's voluntary early food safety review for certain GE crops in the field trial stage and support USDA's oversight. Also, the three agencies do not have a coordinated program for monitoring the use of marketed GE crops to determine whether the spread of genetic traits is causing undesirable effects on the environment, non-GE segments of agriculture, or food safety, as recommended by the National Research Council and others.

USDA, EPA, and FDA have proposed regulatory changes intended to improve their oversight of GE crops. In 2007, USDA assessed a wide array of regulatory alternatives that could redefine, on the basis of risk, which GE crops it regulates and how it will respond to unauthorized releases. USDA's fiscal year 2009 budget request also seeks funding for a voluntary system to help GE crop developers employ best management practices to reduce the risk of unauthorized releases. Furthermore, the 2008 Farm Bill required USDA to take actions on lessons learned from its investigation of an unauthorized release of GE rice. EPA has proposed several changes to its regulations for GE crops that produce pesticides, including one change that would distinguish between pesticidal agents produced in GE crops and those applied topically to crops. In 2001, FDA proposed to require that GE food developers notify the agency before marketing their products. However, as of July 2008, FDA had not taken action to finalize the proposed rule, believing its current approach calling for voluntary notice is sufficient.

United States Government Accountability Office

Appendix 5 – Other Countries' Requirements for GE Crops, Center for Food Safety
(Liz Weiss)

Country	Labeling	Ban or Moratorium on Commercialization	Ban on Imports
Albania		2003	2003
Algeria		2000	2000
Angola			2004
Australia	2001		
Benin		2002	2002
Bolivia		2005	
Brazil	2004	1999-2003	1999-2003
Bulgaria	2005	2005	
Cameroon	2003		
Chile	2000		
China	2002		
Costa Rica	1998		
Croatia	2003	2005	
Equador	2001		2006
European Union (25 countries)	2004	1998-2004	
Georgia		1996	1996
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	2002		
Phillippines	2001		
Russia	2005		
Saudi Arabia	2001	2001	2001
South Africa	2004		2005
South Korea	2002		
Sri Lanka			2000-2001
Switzerland		2005	
Taiwan	2001		
Thailand	2002	2005	1964
Uganda		2004	
Vietnam	2005		
Yugoslavia	2005		
Zambia		2005	2002
Zimbabwe			2002

Appendix 6 – Global Status of Commercialized Biotech/GM Crops: 2008 (Marc Hooper)

1. Soybean

a. 70% (65.8 million has.) of total global soybean planted is biotech.
b. US $4B increase in farmer income in 2007.
c. Countries growing biotech soybean: Argentina, Bolivia, Brazil, Canada, Chile, Mexico, Paraquay, Uruguay, South Africa, USA.

2. Cotton

a. 46% (15.5 million has.) of total global cotton planted is biotech.
b. US $3.3B increase in farmer income in 2007.
c. Countries growing biotech cotton: Argentina, Australia, Brazil, Burkina, Faso, China, Columbia, India, Mexico, South Africa, USA.

3. Canola

a. 20% (5.9 million has.) of total global canola planted is biotech.
b. US $0.4B increase in farmer income in 2007.
c. Countries growing biotech canola: Canada, Chile, USA.

Global Area of Biotech Crops in 2008: by Country (Million Hectares)

Area	Biotech Crops	
1. USA*	62.5	Soybean, maize, cotton, canola, squash Papaya, alfalfa, sugar beet
2. *Argentina**	21.0	Soybean, maize, cotton
3. *Brazil**	15.8	Soybean, maize, cotton
4. *India**	7.6	Cotton
5. Canada*	7.6	Canola, maize, soybean, sugarbeet
6. *China**	3.8	Cotton, tomato, poplar, petunia, papaya, sweet pepper
7. *Paraguay**	2.7	Soybean
8. *South Africa**	1.8	Maize, soybean, cotton
9. *Uruguay**	0.7	Soybean, maize
10. *Bolivia**	0.6	Soybean
11. *Philippines**	0.4	Maize
12. Australia*	0.2	Cotton, canola, carnation
13. *Mexico**	0.1	Cotton, soybean
14. Spain*	0.1	Maize
15. *Chile*	<0.1	Maize
16. *Colombia*	<0.1	Cotton, carnation
17. *Honduras*	<0.1	Maize
18. *Burkina Faso*	<0.1	Cotton
19. Czech Rep.	<0.1	Maize
20. Romania	<0.1	Maize
21. Portugal	<0.1	Maize
22. Germany	<0.1	Maize
23. Poland	<0.1	Maize
24. Slovakia	<0.1	Maize
26. *Egypt*	<0.1	Maize

* 14 biotech mega-countries growing 50,000 hectares, or more, of biotech crops. Developing countries in Italics.

Biotech Crop Traits:

1. Herbicide tolerance (HT)
2. Insect resistance (IR)
3. Virus resistance (VR)
4. Delayed ripening (DR)
5. Stacked traits: IR/HT, IR/IR, IR/IR/HT

Source: Clive James, 2008. Global Status of Commercialized Biotech/GM Crops: 2008. ISAAA Briefs No. 39-2008.

http://www.isaaa.org

Appendix 7 – Reference for Contamination Incidents, Environmental, Social

(Marc Hooper)

Aphis.USDA.gov – Biotechnology:
http://www.aphis.usda.gov/biotechnology/compliance_history.shtml

Biotechnology Noncompliance History

The following is a summary of major incidents of noncompliance with APHIS biotechnology regulations from 1995 through present. In each case, APHIS and the companies took remedial actions in order to protect agriculture, the food supply, and the environment and no adverse effects were reported. Investigative and Enforcement Services (IES) thoroughly investigated each incident. None of the incidents, except those by one company, included field tests of plant-made pharmaceuticals or industrials.

2008

Company/Institution: Syngenta Seeds, Inc. _On April 2, 2008, Syngenta Seeds, Inc. entered into a settlement agreement with APHIS to resolve alleged violations of APHIS biotechnology regulations (7 CFR 340). The incident involved regulated corn seed and it occurred in December, 2006. Specifically, APHIS alleges that Syngenta:

- Failed to notify APHIS of an accidental/unauthorized release within the required time period.
- Failed to contain or devitalize 29 pounds of regulated corn seed when it was no longer in use. This corn seed was subsequently misidentified and disseminated in transit.
- Was responsible for an unauthorized introduction that occurred when corn seed was accidentally released into the environment while in transit.

The regulated parental line was granted non-regulated status in March, 2007.

Resolution: _Under the settlement agreement, Syngenta Seeds, Inc. agrees to pay a civil penalty of $13,125.

2007

Company/Institution: The Scotts Company LLC _On November 26, 2007, in response to an administrative complaint filed against it, The Scotts Company, LLC entered into a settlement agreement with APHIS to resolve alleged violations of APHIS biotechnology regulations (7 CFR 340). Specifically, APHIS alleges that Scotts:

- Failed to comply with performance standards for field trials of glyphosate-tolerant creeping bentgrass (GTCB) conducted under notifications from 1999 to 2005 at multiple test sites located in 19 states,
- Violated supplemental permit conditions for a 2005 Idaho field trial of GTCB by failing to remove immature seed heads, and
- Failed to conduct a 2003 Oregon field trial in a manner that ensured the GTCB and/or its offspring would not persist in the environment.
- In a related incident, APHIS also alleges that Scotts improperly moved GE Kentucky bluegrass seed heads.

Resolution: Under the settlement agreement, Scotts agrees to pay a civil penalty of $500,000. In addition, Scotts agrees to conduct three public workshops within 1 year to present best management practices and technical guidance for other potential developers of GE plants and all interested parties on the identification and prompt resolution of biotechnology incidents. The workshops will take place:

- In Oregon, to address current and ongoing efforts to monitor and destroy GTCB in and around the Oregon Control District,
- At a national conference of seed producers or turfgrass specialists, and
- At a location selected by Scotts, with APHIS approval.

Scotts has already implemented measures to comply with performance standards and permit conditions related to these allegations. In addition, Scotts is carrying out monitoring and mitigation actions in Oregon to locate and remove the regulated GE material that was accidentally released during the 2003 field trial. These actions were required by APHIS beginning in 2004 to address past allegations that Scotts failed to notify APHIS of the accidental release of the GTCB in 2003. The current allegations address the ongoing persistence in the environment related to the accidental release.

Company/Institution: Bayer CropScience

APHIS' Investigative and Enforcement Services (IES), in coordination with USDA's Office of the Inspector General (OIG), conducted an investigation into the release of regulated genetically engineered (GE) material detected in 2 varieties of commercial long-grain rice. APHIS initiated the investigation in August 2006 after Bayer CropScience reported that regulated GE LLRICE601 had been detected in the long-grain rice variety Cheniere. This investigation was expanded in February 2007 to include the discovery of regulated GE material, later identified as LLRICE604, in the long-grain rice variety Clearfield 131 (CL131). Both GE rice lines have the same added protein which has been safely used in other deregulated products for more than 10 years.

Resolution: Investigators were able to determine that the presence of LLRICE601 was limited to the long-grain rice variety of Cheniere and that the presence of LLRICE604 was limited to the long-grain variety CL131. No short- or medium-grain rice varieties tested positive for either LLRICE601 or LLRICE604. Investigators had hoped to identify

how each GE rice line entered the commercial rice supply, but the exact mechanism for introduction could not be determined in either instance. However, direct cross-pollination was probably not a factor for LLRICE604's entry point into CL131.

Based on the findings of the investigation, APHIS is not taking any enforcement action against Bayer. Given the lack of available information and evidence, APHIS was unable to make any definitive determinations that could have resulted in enforcement action. LLRICE601 was deregulated in November 2006, and as such no longer falls under APHIS oversight. In March 2007, APHIS issued emergency action notifications to stop the further distribution and planting of CL131 rice seed to minimize the spread of LLRICE604. The investigation is now closed.

Company/Institution: ProdiGene

On July 26, 2007, ProdiGene, Inc., and APHIS entered into a settlement agreement regarding alleged violations of 7 CFR 340.4(f), which states that a person who is issued a permit must comply with those permit conditions. Specifically, APHIS alleged that ProdiGene failed to monitor for volunteers associated with a 2004 GE field test of a corn variety modified to produce pharmaceutical compounds. APHIS also alleged that the company did not manage the fallow zone properly and allowed oats being grown in the fallow zone to be harvested and baled for use as on-farm animal feed. These alleged violations arose from APHIS inspections of the field test, in which the inspector found volunteer corn growing and flowering within the fallow zone surrounding the field trial and in a nearby sorghum field planted within a 1-mile isolation distance. An APHIS inspector and compliance officer also discovered that oats growing in the border rows immediately surrounding the regulated article had been cut and baled.

Resolution: _ProdiGene destroyed all volunteers in the 1-mile isolation zone, and plowed under the sorghum field. All suspect oat bales were quarantined and later destroyed. An APHIS inspector supervised the destruction of the regulated plant material. The case was referred to IES for investigation. In addition to paying a civil penalty, ProdiGene, Inc., has agreed that it and its successors in interest will never again apply to BRS for a notification or permit to introduce GE organisms.

2006

Company/Institution: BASF

On June 15, 2006, BASF, Research Triangle Park, NC and APHIS entered into a stipulation to settle alleged violations of 7 CFR Part 340.4(f)(4). APHIS alleged that BASF failed to maintain the regulated article only in areas and premises specified in the permit. These alleged violations arose from an APHIS inspection of the field test, in which the inspector noted that the corn was planted in a different location from what was approved in the permit.

Resolution: The case was referred to IES. BASF paid a civil penalty.

Company/Institution: ArborGen, LLC

On July 17, 2006, ArborGen, LLC, Summerville, SC, and APHIS entered into a settlement agreement regarding alleged violations of 7 CFR 340.3(c)(3) and 340.3(d)(2)(ii)(b). APHIS alleged that ArborGen, LLC failed to maintain the identity of trees of a genetic construct introduced in field trials and failed to follow procedural requirements for notifying APHIS of identification of a regulated article in the

notification. These alleged violations arose from a self disclosure by the company that several trees were of a genetic construct not listed on their notification.

Resolution: _The trees have been cut and removed from the location. The stumps are being monitored for re-sprouting and will be treated as appropriate. The case was referred to IES. In addition to paying a civil penalty, ArborGen, LLC employed a third-party consultant to review quality control measures for the management of product identity and inventory. Based on this consultation, ArborGen, LLC presented a written plan to BRS describing how ArborGen, LLC will improve and implement quality control measures. The measures will enhance the genotypic and phenotypic identification of all products that are, will, or may, be regulated articles subject to 7 CFR 340 regulations, including those received from outside contractors.

2005

Company/Institution: Syngenta Seeds, Inc.

On March 24, 2005, Syngenta Seeds, Inc., Research Triangle, NC, and the Animal and Plant Health Inspection Service (APHIS) entered into a Stipulation Agreement to settle alleged violations of 7 CFR Part 340.4 (b) (c). APHIS alleged that Syngenta planted and moved interstate genetically engineered corn seed without obtaining USDA APHIS permits. These alleged violations arose from a disclosure made by the company to APHIS. Specifically, Syngenta mistakenly produced and distributed a limited amount of its genetically engineered Bt 10 corn, which had not complete the Federal government's full regulatory review.

Resolution: _EPA and USDA reviewed the scientific information and concluded that there are no human or animal health or environmental concerns with Bt10 corn due to the limited amount in the environment, the results of the review of product characterization information, and the close similarity of the Bt10 corn line and another Bt corn line which had cleared regulatory review. EPA and USDA coordinated their investigative efforts. All plants of Bt10 corn were destroyed, seed stocks were quarantined, and their disposal was then overseen by USDA. In addition to paying a civil penalty, the Stipulation Agreement required Syngenta to sponsor a training conference for other members of the regulated community that focused on compliance with APHIS rules regulating biotechnology crops (7 CFR Part 340). The conference goals were:_1. Develop best management practices or technical guidelines for insuring no contamination or cross contamination of biotech genes in the seed development and breeding program; and_2. Develop best management practices or technical guidelines to identify, promptly address, and implement corrective measures to resolve unintended biotech releases.

2004

Company/Institution: Seminis Vegetable Seeds, Inc.

On September 30, 2004, Seminis Vegetable Seeds, Inc., Oxnard, CA, and APHIS entered into a stipulation to settle alleged violations of 7 CFR Part 340.3 (c) (1). APHIS alleged that Seminis shipped small amounts of genetically engineered tomato seeds to the University of California (UC), Davis, without proper identification. APHIS also alleged that UC inadvertently shipped these seeds to multiple US and international investigators. Seminis retrieved seeds and documented seed locations. In addition to paying a civil penalty, the company was required to implement training and procedures to prevent future violations.

Company/Institution: The Scotts Company

On August 3, 2004, the Scotts Company of Marysville, OH, and APHIS entered into a stipulation to settle alleged violations of permit conditions requiring the immediate notification upon discovery of accidental or unauthorized releases of regulated articles. [7 CFR 340.4 (f)(10)(i)]. APHIS alleged that, on two occasions, Scotts failed to notify APHIS about the accidental release of glyphosate-tolerant, or Roundup Ready, Creeping Bentgrass (GTCB), which resulted from unanticipated wind events at a field test site in Jefferson County, OR that carried dried GTCB seed heads beyond the field test location.

Resolution: Scotts provided a mitigation plan and committed to additional control measures outlined in a Compliance Agreement with BRS. In addition to paying a civil penalty, Scotts was required to implement training and procedures to prevent future violations.

2003

Company/Institution: Pioneer Hi-Bred International, Inc.

IES initiated an investigation in May of 2003 after tests required by the Environmental Protection Agency indicated a small amount of genetically engineered corn had cross contaminated surrounding genetically engineered corn being grown at the research nursery. Of the 337,000 leaf and seed samples collected from the surrounding research fields, 12 leaf samples indicated cross contamination had occurred. All of the corn planted at the Pioneer nursery was for use in research breeding trials and was not to be used for food or feed.

Resolution: The cross-contaminated research corn was destroyed immediately upon discovery. Following a thorough investigation into Pioneer Hi-Bred International, Inc.'s adherence to BRS-imposed confinement conditions, IES determined that no conditions of the APHIS permit were violated. In addition, no unapproved corn plants entered the food or feed supply. The investigation is now closed.

2002

Company/Institution: ProdiGene

Location 1: APHIS inspectors found volunteer corn growing within a soybean field that had been a field test site for a pharmaceutical-producing plant in the previous season. Commercial corn surrounded the site within the appropriate isolation distance. ProdiGene failed to notify APHIS of volunteers with tassels within 24 hours of discovery.

Remedial measures: ProdiGene destroyed all corn seed and plant material within 1320 feet of the previous year's test plot. APHIS inspectors supervised the destruction of the regulated corn seed and plant material.

Location 2: At a second location, APHIS inspectors found volunteer corn from the previous year's test sites with tassels growing in a soybean field. APHIS required the company to remove all the volunteer corn to prevent its harvesting, along with the soybeans. Despite APHIS notification of appropriate volunteer corn removal, the soybean field was harvested with volunteer corn plants standing in the field. The soybeans were sent to a grain elevator where they were mixed with 500,000 bushels of soybeans.

Remedial measures: APHIS and the company stopped movement of all the soybeans at the elevator. USDA destroyed the 500,000 bushels of soybeans.

Joint Resolution: IES investigated both incidents and through a formal administrative proceeding, ProdiGene is paying a $250,000 penalty to resolve the allegations. ProdiGene also entered into a consent decision with USDA. ProdiGene agreed to reimburse USDA for the cost of moving and destroying 500,000 bushels of soybeans and provided proof of financial responsibility of $1 million trust fund. In addition, the company agreed to develop a new compliance implementation program and engage in an audit by a third party; ProdiGene must comply with the auditor's requirements.

2001

Company/Institution: North Carolina State University

USDA's Office of the Inspector General (OIG) inspected field test sites of transgenic tobacco engineered for virus resistance and determined that the N.C. State researcher did not have a current permit. The field test was near completion when OIG discovered the infraction.

Resolution: APHIS required the researcher to monitor the site in the following year. IES investigated the case and North Carolina State University paid a stipulated penalty of $1,250.

Company/Institution: Monsanto

Monsanto failed to monitor for corn volunteers in the year following a GE crop field test on an insect-resistant corn variety. The company allowed the volunteers to release pollen within commercial corn planted over the field test site. Consultants and other field workers reported the issue of corn planted on the previous test site to Monsanto, but the company failed to take immediate action or report the situation to APHIS.

Resolution: Monsanto destroyed all the corn planted on the site of the previous years' test crop. Monsanto also purchased and destroyed all the corn growing within the isolation distance. IES investigated and Monsanto paid stipulated penalty of $12,500. Patriot Seed, their cooperator, paid a stipulated penalty of $3,750.

Company/Institution: Monsanto

Monsanto did not follow APHIS' permit conditions for border rows of cotton. The border rows on this field test were too small.

Resolution: Once the infraction was detected, Monsanto destroyed all of the cotton. IES investigated and Monsanto paid a stipulated penalty of $25,000. Monsanto's cooperators paid the following stipulated penalties: University of Tennessee $3,750; Delta and Pine Land $15,000; University of Georgia $3,750.

1998

Company/Institution: University of Hawaii

Contrary to assigned permit conditions, 15 papaya plants genetically engineered for virus resistance were allowed to grow on an experimental plot. APHIS was notified after the plants had been present for 3 to 5 months. Pollen from these 15 plants would have been able to fertilize nontransgenic trees. An APHIS inspector was sent to the site to investigate and determined that the nearest papaya trees were one-quarter of a mile away, which is an adequate isolation distance to prevent fertilizing nontransgenic plants. The inspector also took immediate steps to cut down the 15 plants and remove all flowering parts containing pollen.

Resolution: IES investigated the case and the University of Hawaii paid a stipulated penalty of $500. A written warning had already been sent to the permit holder for infractions at another test site.

Company/Institution: Monsanto

Monsanto planted three GE crop field tests in Puerto Rico and one GE crop field test in Illinois without notifying APHIS. Several field tests included plants engineered with insect resistance. Other field tests included plants engineered with glyphosate resistance. The company also moved regulated GE material without notifying APHIS.

Resolution: _Monsanto accounted for all the GE corn seed. All the GE corn seed was either in storage or planted as a regulated article under a new APHIS permit. Monsanto destroyed any regulated articles in the field not under an APHIS permit. Monsanto improved their experimental tracking database and provided training for the relevant field personnel. IES investigated and Monsanto paid a stipulated penalty of $2,500.

1997

Company/Institution: Monsanto

Monsanto failed to monitor for canola volunteers in the year following a GE crop field test that modified the corn's oil profiles at numerous locations. The company also failed to notify APHIS within 24 hours once the lapse in monitoring was detected.

Resolution: Monsanto removed the canola using herbicides. At one location, the volunteers were located within the isolation distance of a commercial birdseed canola crop. APHIS required the company to purchase and destroy the crop that could have been pollinated by the volunteers. APHIS also required Monsanto to monitor the sites for one year and destroy any additional volunteers. IES investigated the case and Monsanto paid a stipulated penalty of $3,300.

1995

Company/Institution: Harvey Campbell and Associates, Inc.

The company planted cotton seed with genetically engineered herbicide resistance in California without obtaining a permit or requesting permission to release the cotton into the environment. In addition, the company had received APHIS permission to move the cotton, but provided inaccurate information about the name and address of the person receiving the GE cotton seed. The 40-foot border rows of nontransgenic cotton surrounding the field test were harvested and pressed for oil, which was used in animal feed.

Resolution: An APHIS officer visited the site to verify that all of the GE cotton plants were destroyed. All of the cotton seed and lint that was harvested from the GE crop was also ordered to be seized and destroyed. As a result of cross pollination, the 40-foot border rows of nontransgenic cotton could have contained some GE material, however, the cotton seed oil would have been free of all GE proteins. The case was referred to IES, and Harvey Campbell and Associates paid a stipulated penalty of $500.

Chapter 2, Tracking and Monitoring

Appendix 8: Buffer distances

The following distances are recommended by the Seed Savers Exchange. For additional details see Suzanne Ashworth, *Seed to Seed,* (Decorah, Iowa, 2002)

5-10 miles: spinach
One mile: *Brassica oleracea* (broccoli, cauliflower, cabbage, kale), corn (including popcorn), okra (although insect pollinated), onions.
one-half mile: beets (including swiss chard, radish, runner beans (cross-pollinate with other runner beans)
quarter mile: arugula, carrots (from other carrots and wild Queen Anne's Lace), watermelons, malabar spinach (doesn't cross with regular spinach), cucumbers, eggplant, "melons" (cantaloupes, muskmelons, honeydew, snake melon and Armenian cucumbers), squash (within the same species: *C. maxima, C. mixta, C. moschata and C. pepo*), gourds.
Miscellaneous shorter distances: peppers (separate by at least 500'), 'peas (separated by 50'), lettuce (slight chance of cross-pollination so separate by 25' from other varieties that are going to seed), tomato (cross-pollination between modern varieties seldom occurs, except in potato leaf varieties which should be separated by the "length of the garden").
Do not cross pollinate: garden beans, soybeans, tomatillo, garden huckleberry (*Solanum melanocerasum*)

NB: a number of these crops are biennials, and cross-pollination would not ordinarily be a problem unless they are being deliberately allowed to go to seed. Persistence of the hybrid form in the genome would also depend on the seed being saved for future use.

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Other buffer information
Alfalfa: two fields each less than 5109 feet from a given beehive might cross, which extrapolates to a buffer distance approximating two miles.
(http://www.ars.usda.gov/is/AR/archive/oct01/pollen1001.htm)

Chapter 3, Economic Impacts

Appendix 9: GE and non-GE Commodity Prices

Note: as of **4-14-09** GMO Soybeans were selling on CBOT for $9.30 – 10.28 / bushel

Buyer	Product	Non-GMO Premium
Zeeland Farms, Inc www.zfsinc.com 800-748-0595	Non-GMO low saturated fat soybeans " low linolenic soybeans " regular soybeans	$1.75 / bushel $1.50 / bushel $1.00 / bushel
Huron Commodities Monticello IL 217-762-2450	" Soybeans, various 2006-2008 short of quota, 2009 met quota	$1.50 – 1.80 over CBOT
Mid Michegan Specialty Crops, LLC Ithne MI 989-875-6672	Non-GMO Food grade soybeans (full this year, did not fill quota in 2008)	Premiums paid Contact for details
Solae Company (Dupont) Johnston, IA 800-247-6803	Non-GMO Food grade soybeans Contracted in advance only	$1.00 over Cargill, Inc
Nutritional Blending Inc New Paris, IN 800-285-0796	Non-GMO "Soybeans for roasting"	$ .55 / bushel (over ?)
Unity Seed Company Casselton ND 800-927-8947	"Premiums have increased steadily over the years as fewer acres have been planted to non-GMO products. The time has never been better to be a non-GMO soybean producer… Currently we have a need for 2008 non-GMO soybeans as well as producers for 2009 crop non-GMO soybeans. Please contact us for premium information."	
ADM Grain Company Decatur, IL 217-451-4955	Contracting for non-GMO soybeans, non-GMO corn	Premiums paid Contact for details
Brushvale Seed Inc Breckenridge, MINN 218-643-2311	Contracting for non-GMO soybeans	Premiums paid Contact for details
Citizens LLC Charlotte MICH 605-271-7471	Food grade non-GMO soybeans	$.75 – 2.00 over CBOT depending on variety
Clarkson Grain Co Cerro Gordo, IL 800-252-1638	Non-GMO pioneer 93B82 soybeans, non-GMO white corn varieties	Premiums paid Contact for details
DeBruce Grain, Inc Creston, Iowa 877-274-2676	Non-GMO soybeans	Premiums paid Contact for details
Grain Millers Specialty Products Eden Prairie MINN 952-983-1331	Non-GMO soybeans	Premiums paid Contact for details
Grain Place Food, Inc Marquette NEB 888-714-7246	Non-GMO popcorn, peas, barley, oats, millet, soybean, corn	Premiums paid Contact for details
Midwest Farmers Cooperative Montana Specialty Mils LLC Northland Seed & Grain Corporation Pacific Soybean & Grain Premium Ag Products Cooperative Professional Proteins, Ltd Richland Organics SB&B Foods Inc Stonebridge Ldt Thompsons Ltd	More buyers offering premiums for non-GMO	Contact for details

1) Australian canola market has expanded hugely to meet European demand for non-GMO soy.
2) Japan huge market for non-GMO canola, soybeans & hay (wont buy RR alfalfa)

Chapter 3, Economic Impacts

Appendix 10: Comparative Controls on Corn Earworm

Sky Hoyt's SAFE corn without worms - how?

Answer: Using a new naturally occurring selective insecticide, spinosad, vegetable oil, and a new specially designed applicator I am controlling corn earworms without the use of potent persistent poisons or genetically modified seeds. At this time, results are better than expected!

What is spinosad? It was discovered in fermentation samples of Caribbean soil and found to be active on corn earworm. Spinosad has low toxicity to mammals (humans) and birds. It is approved for use up to 1 day of harvest. The active ingredient is used in both organically approved and non-organically approved products. I have chosen to use the non-organically approved version (trade name Success) primarily due to the cost ($470) of the organically approved version (trade name Entrust). I cannot determine any significant difference between the two versions, other than one is a liquid and the other is a powder.

What is the applicator? Called a Zealater, it was developed at the University of Massachusetts to place a measured dose of oil and pesticide in corn ears directly above the tip of the ear in the silk channel where the corn earworm enters. This precise placement allows "gentler" pesticides to have greater effect.
Additional applications may be made if worms are detected. Future plans include trapping the moths that lay the worm's eggs to determine more accurately how many pests are present.

Corn earworms are a very difficult pest to control and they are widespread. Typical mass market production requires the use multiple applications of potent persistent pesticides or genetically-modified seeds that produce their own pesticide. This SAFE technique is a bold breakthrough alternative approach!
4-09-09

Sky estimates that costs for this technique are approximately "15 cents per ear per application. In my mind I think the total cost is about 25 cents per harvested ear" (because two applications are sometimes required). According to the Rupp Seeds 2009 Catalog, most genetically engineered Bt varieties of sweet corn seed cost $7.90 per 1000 seeds, with prices for non-GE varieties ranging from $4.85 to $5.90[1]. At two seeds and two ears per plant the additional cost per 1000 ears would range from $2 to $3.05—negligible in comparison to the costs of the SAFE method detailed above. The subcommittee did not evaluate costs or risks associated with a traditional pesticide spray program to control earworms.

Whether planting genetically engineered Bt corn for earworm control would actually be advantageous for the grower would depend on additional factors not addressed here, with the most important by far being potential market resistance.

[1] Rupp Seeds 2009 commercial vegetable price list, http://www.ruppseeds.com

Chapter 3, Economic Impacts

Appendix 11: "Is It Organic?"– the SAFE method of cultivation

Sky Hoyt Specialty Grower: Lakeport, CA 707-279-0859, 866-SKY-HOYT

Is this produce Organic? No. I use a growing standard called SAFE, which uses many organic methods along with synthetic fertilizers, and avoids dangerous pesticide contact with food crops.

The affects of conventional farming on personal health, as well as the local and global environment, are concerns that I believe are valid. SAFE is a conscientious, small-farm alternative approach to industrialized farming. I am committed to carefully choosing the highest quality farming practices that are continually being better understood, discovered, and available. Over 30 years of experience, that began with a commitment to Organic, has taught me that by integrating the best aspects of both organic and non-organic farming practices I am able to sustainably grow better quality food.

The core principles of SAFE farming are:

1. Providing optimum plant nutrition to develop maximum pest resistance, flavor and nutritional value in crops. Eliminating soil depletion and increasing organic matter in soil creates healthy plants. Along with natural fertilizers, SAFE allows synthetic fertilizers (concentrated plant nutrients) to help build soil fertility and sustain soil health.
2. Using natural, effective pest treatments whenever possible and only when needed to decrease pesticide use. Many people think that "Organic" means no spraying and no pesticides. However, there are organic farmers who use organically approved sprays and pesticides. SAFE only uses pesticides with an EPA (U.S. Environmental Protection Agency) rating of a 0 or 1 day PHI (pre-harvest interval). This helps protect the environment, farm workers, and my customers.
3. Using historically safe, time honored, and biologically based methods. SAFE pledges to not knowingly buy, grow, or sell genetically engineered or modified seeds or plants.

SAFE uses natural approaches that are often identified as Organic such as:

1. Beneficial insect release, such as ladybugs and predator mites.
2. Rotation of food crops, and cover crops for soil improvement.
3. Fertilizing with gypsum for calcium enrichment and mineral balance.
4. Seaweed for soil enrichment.
5. Growing "trap" crops to attract pests away from food crops.

Thank you very much for your care and interest in this matter. If you would like to obtain additional information, give valued input, or ask further questions, feel free to call toll-free 866-SKY-HOYT.
July 22, 2008

Chapter 7, Religious Issues

Appendix 12: letter from Sarah Ryan, Environmental Director, Big Valley Rancheria, April 2009: Cultural Impacts of Genetically Engineered Crops

An important aspect to consider when reviewing the full impacts of allowing genetically engineered crops in Lake County is the impact to cultural practices. Cultural practices, which in this case is defined as traditional practices of the native cultures in Lake County, can be forever altered by the presence of genetically engineered crops. The primary threat to cultural practices is in transgene flow to wild varieties of plants.

Archeologists date Pomo Indian presence in this area back to at least 11,000 years ago. In prehistoric times, Native peoples were hunter gathers and relied on the bounty of wild plants in the Clear Lake region. In modern times, these plants continue to be used in traditional ways for medicines, foods, spiritual ceremonies and other cultural practices. The use of 'wild' varieties of grasses and other plants that are located in public and private areas are an important component of Tribal culture. In addition, "[Native] plants are a cornerstone of biological diversity," according to the California Native Plant Society as stated on their website (http://www.cnps.org). Because biological diversity is necessary for a thriving ecosystem, Native peoples consider that anything that limits biological diversity will threaten their culture practices and ultimately, their culture.

During the Measure H Campaign to ban genetically engineered crops in Mendocino County in 2004, a Pomo GMO Statement developed amongst Tribes was submitted. A portion of it reads, "We therefore proclaim that the attempts now being made to forever alter our fish, trees, flowers, grasses and all other living things around us in unnatural ways are a threat to the preservation of our cultural traditions."

As experience has shown, the pollen from genetically engineered crops does not recognize boundaries. Besides accidental pollination of nearby conventional or organic crops, many studies have shown that domesticated plants also cross with their wild relatives (Ellstrand, N. C., H. C. Prentice, and J. F. Hancock. 1999. *Gene flow and introgression from domesticated plants into their wild relatives*. Annual Review of Ecology and Systematics 30:539-563; Rissler, J., & Mellon, M. (1996). *The ecological risks of engineered crops*. Cambridge, MA: MIT Press.)

The following table lists domesticated plants that are known to cross with their relatives (Gene Flow from Transgenic Crops to Wild Relatives: What Have We Learned, What Do We Know, What Do We Need to Know? N. C. Ellstrand, presented at Gene Flow Workshop, The Ohio State University, March 5 and 6, 2002)

Table 1 There is more than circumstantial evidence for natural hybridization between the following domesticated plants and one or more wild relatives (Ellstrand 2003)

Cultigen	**Scientific name**
Alfalfa	*Medicago sativa*
Apple	*Malus x domestica*
Avocado	*Persea americana*
Banana	*Musa acuminata*
Bean, common	*Phaseolus vulgaris*
Beet, sugar	*Beta vulgaris*
Bentgrass, creeping	*Agrostis stolonifera*
Cacao	*Theobroma cacao*
Cane, sugar	*Saccharum officinarum*
Cassava	*Manihot esculenta*
Cocona	*Solanum sessiliflorum*
Coffee, arabica	*Coffea arabicab*
Cotton	*Gossypium barbadense*
Cotton	*Gossypium hirsutum*

Elm, Siberian	*Ulmus pumila*
Fescue, tall	*Festuca pratensis*
Gourd	*Cucurbia pepo*
Grapes	*Vitis viniferab*
Juniper	*Juniperus chinensis*
Lettuce	*Lactuca sativa*
Maize	*Zea mays* ssp. *mays*
Millet, foxtail	*Setaria italica*
Millet, pearl	*Pennisetum glaucum*
Mushroom, button	*Agaricus bisporus*
Oats	*Avena sativa*
Potato	*Solanum stenotomum*
Potato	*Solanum tuberosum*
Quinoa	*Chenopodium quinoa*
Radish	*Raphanus sativus*
Rape, swede	*Brassica napus*
Rape, turnip	*Brassica campestris*
Raspberry	*Rubus idaeus*
Rhododendron, catawba	*Rhododendron catawbiense*
Rice	*Oryza glaberrima*
Rice	*Oryza sativa*
Rye	*Secale cereale*
Ryegrass	*Lolium perenne*
Salsify	*Tragopogon porrifolius*
Sorghum	*Sorghum bicolor bicolor*
Soybean	*Glycine max*
Squash	*Cucurbia pepo*
Strawberry	*Fragaria x ananassa*
Sunflower	*Helianthus annuus*
Walnut	*Juglans regia*
Watermelon	*Citrullus lanatus*
Wheat, bread	*Triticum aestivum*
Wheat, durum	*Triticum turgidum durum*

This table lists several plants, including their wild varieties, that the Native peoples in Lake County use for cultural practices. Some of the plants on this list have genetically engineered counterparts (sugar beets, alfalfa, creeping bentgrass, and soybean, for example). Genetically engineered crops in the county could easily alter wild varieties which are important to Tribal cultural practices. If this occurred, it would change the genetics and very nature of the plant in a way that would be abhorrent to some and sacrilege to others. The altering of a plant's genetic nature (and consequent permutations) cannot be undone and would have a lasting impact on cultural practices among the Native peoples in the Clear Lake region.

Chapter 8, Social and Ethical Issues

Appendix 13: Some facts about Agriculture in California and the Nation

In 2007 California farmers and ranchers received a record $36.6 billion in revenues. California is home to the most productive agricultural counties in the nation. California produces almost half of the fruits, nuts, and vegetables grown in the United States. The number of farms operating in California during 2007 fell to an estimated 75,000, less than four percent of the national total. U.S agriculture employs 21 million people—more than seven times as many workers as the U.S. automotive industry. According to a 2006 USDA study, agricultural exports generated 841,000 full-time civilian jobs, including 482,000 jobs in the non-farm sector.

Americans spend just 9.8% of their income on food—less than consumers in any other country.

U.S. farms sold $297 billion in goods in 2007—that's bigger than the GDP of Ireland, Finland, Hong Kong or the United Arab Emirates.

For every dollar Americans spend on food, farmers only get 20 cents.

Of the $4.49 retail price of an 18oz box of cereal, farmers receive just 9¢.

Of the $2.99 retail price of a 1lb loaf of bread, farmers receive just 12¢.

91% of Americans think it is important to produce food domestically.

Families, farmer partnerships or co-ops run 95% of U.S. farms—less than 5% are corporate farms.

Today's farmer provides food and fiber for about 140 people—up from just 19 people in 1940.

America has the cheapest, safest, most abundant food supply in the world.

There were 13.4% more women farmers in 2002 than in 1997.
(From Farm Policy Facts 2009)

Even Presidents and almost Presidents love farmers:

"Our farmers deserve praise, not condemnation; and their efficiency should be cause for gratitude, not something for which they are penalized." - President John F. Kennedy

"Cultivators are the most valuable citizens…they are tied to their country." - President Thomas Jefferson

"Burn down your cities and leave our farms, and your cities will spring up again as if by magic; but destroy our farms and the grass will grow in the streets of every city in the country." - William Jennings Bryan

APPENDIX 10: A Recommendation Concerning the Regulation of Genetically Engineered Crops with the County of Lake, January 25, 2010

A RECOMMENDATION CONCERNING THE REGULATION OF GENETICALLY ENGINEERED CROPS WITHIN THE COUNTY OF LAKE

THE LAKE COUNTY GENETICALLY ENGINEERED CROPS ADVISORY COMMITTEE

PHASE II MEMBERS:

Victoria Brandon
Lars Crail
Melissa Fulton
Lorrie Gray
Marc Hooper
Andre Ross
JoAnn Saccato
Michelle Scully
Bob Zolier

PLEASE NOTE: The "Phase II" members of the Advisory Committee wish to thank each and every one of the following members and alternates who participated in the lengthy, and sometimes arduous, "Phase I" of the Advisory Committee's work process: Deb Baumann, Glenn Benjamin, Steve Devoto, Jeff Gleaves, Stephen Grammer, Larry Heine, Sky Hoyt, Paul Lauenroth, Sequoia Lyn-Franklin and Liz Weiss. In addition, we wish to thank Lake County Agricultural Commissioner Steve Hajik, Deputy Administrative Officer Debra Sommerfield, Supervisors Rushing and Brown, and all of the other kind folks who made positive contributions, both large and small, to the Advisory Committee's work process. Without the energy, commitment, patience and stamina of all concerned we would not have been able to come up with the attached recommendation. It is our hope that the Board of Supervisors, and the community at large, will find our recommendation to be useful in addressing an issue which is both topical and serious. In the course of our work we have made every effort to adhere to the Advisory Committee's original mission: *Through common consensus, make a simplified recommendation regarding GE crops that addresses underlying factors and that is fair to all of Lake County.*

Lake County Genetically Engineered Crops Advisory Committee
January 25, 2010

To: Board of Supervisors for the County of Lake
From: Lake County Genetically Engineered Crops Advisory Committee
Date: January 25, 2010
Re: Advisory Committee recommendation concerning the regulation of genetically engineered crops in the County of Lake

The following recommendation is comprised of nine (9) paragraphs of proposed language for a county ordinance/regulatory framework which would, upon adoption, provide for the registration and monitoring of commercial cultivation of genetically engineered crops in the County of Lake.

All of the language proposed herein was the subject of much deliberation and debate by all of the members of the Advisory Committee. Much of the language proposed herein was adopted under the rule of "consensus minus one." Some reservations were voiced regarding specific words chosen. In addition, there are a number of unresolved policy issues which, it was decided, were outside of the Advisory Committee's purview.

The Advisory Committee hereby submits its own recommendation regarding what a fair and practical regulatory framework for the commercial cultivation of genetically engineered crops in the County of Lake might conceivably look like.

January 25, 2010 Respectfully submitted,

Lake County Genetically Engineered
Crops Advisory Committee

RECOMMENDATION

The nine (9) paragraphs for a recommended regulatory framework are as follows:

1. **Paragraph 1:**

   a. Commercial GE crops may only be grown in Lake County with advance registration obtained from the Agricultural Commissioner (AC). Alternatively registration may be obtained from the California Crop Improvement Association (CCIA). The registration shall stipulate the use guidelines set by the AC in consultation with the GE Advisory Committee, which shall be the

a. GE crop guidelines established by the Agricultural Commissioner in consultation with the GE Advisory Committee shall be based on results of scientific research and shall consider the possibility of gene flow into neighboring commercial non-GE crops and native plants.

(1) Consensus Approval on January 11, 2010: 7-Yes; 0-No.

b. The guidelines shall be agronomic in nature and designed specifically to address the growing of the GE crop.

(1) Consensus Approval on January 11, 2010: 7-Yes; 0-No.

c. *Paragraph 4 Part c^1 and c^2 – No Consensus:*

c^1 Appropriate buffer zones as suggested in scientific literature and testing reports shall be stipulated so that gene flow above a de minimus level of 0.1% for seed crops, 0.3% for food crops, and 0.9% for animal feed and native plants is not expected.

(1) No Consensus: 5-Yes; 2-No; January 11, 2010.

c^2 Appropriate buffer zones as suggested in scientific literature and testing reports shall be stipulated so that gene flow above a non-detectable level is not expected

(2) No Consensus: 2-Yes; 5-No; January 11, 2010.

d. Any decision by the Agricultural Commissioner with regards to GE crop guidelines may be appealed to the Board of Supervisors.

(1) Consensus Approval on January 11, 2010: 7-Yes; 0-No.

5. **Paragraph 5:**

a. Upon request, pertinent registrar will advise whether or not a specified GE crop is planted within a two mile radius of a particular point of origin. The exact location of said GE planting will not be publicly disclosed.

(1) **Consensus Approval on January 18, 2010: 5-Yes; 0-No.**

9. **Paragraph 9:**

a. No later than five (5) years from the date of establishment, this registration process may be re-visited by the Lake County Board of Supervisors.

(1) **Consensus Approval on January 18, 2010: 5-Yes; 0-No.**

Dissenting Opinion

Submitted January 26, 2010 by
JoAnn Saccato, Lars Crail & Lorrie Gray

Members of the Lake County Genetically Engineered Crops Advisory Committee

Paragraph 4 - Expected Levels of Contamination When Considering Buffer Zones

Some members of the GE committee were intent on creating a situation of co-existence of both GE crops and non-GE crops in Lake County. Some members believe this is an impossible scenario and see the GE issue as a property rights issue with GE technology being forced upon an unwanting public. Through lack of disclosure and uncontrolled means, the technology has already created harm. One need only look to the debacle in the rice market from GE contamination to see the potential for harm for producers[1]. To insist that the technology be accepted through the acceptance of de minimis levels of expected gene flow contamination when considering buffer zones is an example of the technology being forced on an unwanting public. We believe that "undetectable levels of expected contamination" when considering buffer zones is a better example of co-existence.

When it comes to agricultural practices, there is the understanding of "first in time, first in right". This would include the ability to continue to market crops as they are intentionally grown (e.g. organic as organic, non-GE as non-GE) given the introduction of a new technology.

Organic production is process, not product, based. In organic production, genetic engineering is an excluded method.[2] The National Organic Program (NOP) does not address gene flow or adventitious contamination in the finished product specifically, instead leaving it to the marketplace to determine acceptability. While it is clear that an organic producer would not lose certification due to unintentional GE contamination, it is not clear, when left up to the marketplace, whether a contaminated crop can be sold as organic. If an organic farmer loses the ability to sell their crop as organic, they may lose a premium normally paid for their product. In addition, if the contaminated crop is accepted and sent to market as organic, the public that purchases organic to be protected from GE technology is no longer protected.

If contamination occurs and the producer is unable to sell their crop at the premium afforded in the marketplace for GE-free product, there is no legal remedy system in place for the producer to recover the loss except for possible redress in civil court. It is

[1] http://www.greenpeace.org/canada/en/campaigns/ge/latest-developments/costly-genetically-engineered-contamination & http://www.stuttgartdailyleader.com/news/x469160676/Farmers-amend-lawsuit
[2] 7 CFR Part 205 § 205.105 & 205.2

acceptance of a di-minimus standard of expected contamination when determining buffer zones is not acceptable or fair to all of Lake County. We believe that "undetectable levels of expected contamination" when determining buffer zones is more fair to the non-GE producers, the public that does not want GE products, and the environment at large.

To: Lake County Board of Supervisors
From: Marc I. Hooper, Kelseyville Resident
Date: January 28, 2010
Re: Support of the Growing of Biotechnology Crops in Lake County

I am submitting the following for Board consideration as an alternative to proposals or recommendations that would regulate Genetically Engineered Crops in Lake County.

Agriculture is a leading industry in Lake County. Lake County agriculture is diverse. In 2008, the gross agricultural production was over $61.3 million dollars, down 10% from $70.7 million in 2007. Associated industries involved in the processing of agricultural commodities result in a "multiplier effect" so that agriculture's contribution to the local economy each year is significantly greater.

Because of the importance of agriculture to the local economy and the community way of life in Lake County, it is crucial that local growers are able to utilize the wide range of technologies available in order to produce a safe, healthy and affordable food supply. The use of biotechnology in agriculture has many benefits including: crop varieties which have been developed to ward off pests, resist particular herbicides, resist plant diseases, and tolerate adverse growing conditions, as well as improving production and reducing costs.

Biotechnology in agriculture is sometimes referred to as genetic modification or genetic engineering (GE) of crops. In crop production, some major goals of genetic modification are to: reduce the need for chemical pesticides and herbicides; reduce water use; increase nutritional quality; increase food safety; improve plant quality for storage; and increase yields. Genetic modification has been in existence for thousands of years, when people first began crossbreeding plants to produce better foods and fiber. Modern genetic modification began in 1953 when scientists discovered the structure of DNA. Since then, researchers have learned how to move genetic material from one plant to another. For most crops, the seed is the delivery system through which advances in plant genetics and biotechnology are transferred into agricultural production. Genetically modified seeds can better protect crops against diseases, pests and weeds, and can generate improved products.

Biotechnology has been the subject of voter initiatives in California. The initiatives were intended to prohibit the use of biotechnology, including genetically engineered (GE) or genetically modified organisms (GMO's) and were placed on ballots by those opposed to the use of such technologies. To date, there are four counties that have passed Anti-GE ordinances they are: Marin, Mendocino, Santa Cruz and Trinity. Anti-GE ordinances have failed in four

Individual Comments and Recommendations Concerning Paragraph 4C, Proposal to Register Genetically Engineered Commercial Agricultural Production on a Crop by Crop Basis

Broc Zoller, Marc Hooper and Michelle Scully

Submitted 1-27-2010

Getting Crops from field to the ultimate consumer is a complicated process. In order to assure buyer satisfaction, standards of purity routinely are agreed to between buyer and producer. Amounts of unwanted contamination are specified in contracts as a matter of business in the agricultural world. These standards may be enforced by inspection procedures agreed to by buyer and seller.

As the predominance of GE products in some commodities such as corn and soybeans in world trade has grown, this requirement has been necessarily overtaking the world in separating GE from non-GE crops in the last 20 years. This has been occurring in both organic and conventional markets. For example, because the transit chain can contain both GE and Non-GE commodities, there has been opportunity for inadvertent mixing that buyers have found need to address in some cases with purity standard testing. These standards, while not present in all markets, have primarily been centered around the use of *de minimis* contamination levels no greater than 0.9% as an operational standard. Trade of non-GE products is certified by testing to be at least 99.1% free of GE products and is accepted in markets using these procedures as GE free according to buyer agreements (2,3,4,5,6,7).

The effort to maintain absolute purity was thus given up as impractical in these markets. The impracticality of an absolute non-detection of contamination standard for determining acceptable purity has been accepted in most if not all cases, where potential impurity of various origins exists in agricultural trade. In some cases, higher levels of contamination may be allowed.

For example, a grape delivery contract may contain a clause allowing rejection of loads showing defects (such as decay, freeze damage, skin breaks from bird damage, and etc) in excess of 1.5% by weight or 1% by weight of material other than grape (MOG). Pear processing delivery contracts routinely have specified freedom from grounders not above 2 % of a load and worms or worm holes not above 5%. Fresh graded boxes of pears may not exceed 4% for serious insect damage or 2% for decay.

In the case of seed crops, the standard of purity is often highest (= lowest level of impurity allowed), especially in the case of certified seed. If the production is certified, the field must be separated by agreed upon buffer distances from potential pollen contamination sources. These buffers are facilitated in California by registration with the California Crop Improvement Association (CCIA), which monitors compliance and issues certification. The CCIA is officially recognized as the seed certifying agent under California seed law. As an example, certified alfalfa seed may contain no more than 0.5% inseparable other variety or crop seeds and must be separated from other in field varieties by at least 165 feet. Samples of certified seed at harvest must contain no more than 0.1% other crop seed (1,7,8).

The use of *de minimis* levels of impurity is thus firmly entrenched in the agricultural world. Although the final vote was not at the consensus level (at least 6 of 7 members supporting), ***not to exceed de minimis levels of GE contamination for the case by case regulation of Lake County crops were supported by 5 of 7 voting members of the Lake County GE Committee in paragraph 4C.***

of gene flow in the scale up and commercial use of biotechnology-derived crops: Economic and policy considerations. Council for Agricultural Science and Technology (CAST) Issue Paper Number 37, December 2007. http://www.cast-science.org

6. Roseboro, Ken, Editor/Publisher (2008). Non-GMO verification of organic foods to start. The Organic and Non-GMO Report 8(4):4. http://www.non-gmoreport.com

7. Roseboro, Ken, Editor/Publisher (2009). EU revises organic rules, clarifies GMO prohibition. The Organic and Non-GMO Report 9(6):6. http://www.non-gmoreport.com

8. Van Deynze, Allen E., Sharie Fitzpatrick, Bob Hammon, Mark H. McCaslin, Daniel H. Putnam, Larry R. Teuber and Daniel J.Undersander (2008). Gene flow in alfalfa: Biology, mitigation, and potential impact on production. Council for Agricultural Science and Technology (CAST) Special Publication Number 28, September 2008. http://www.cast-science.org

#1
We are concerned with a registration process with a county agency. The issue was discussed during many committee meetings as to whether the registration information could be held confidential within a county agency. We believe a third party registrar provides the highest degree for grower confidentiality.
Some on the County Committee were adament about the option of local registration, hence the Agricultural Commissioner was added as an option.

#2.
We support the five member committee to be appointed by the Supervisors.

#3.
We support this, as the list can be available to those growers interested in growing crops with this type of technology.

#4
We support the minor edits made by the committee. We support the current stated *de minimus* level of 0.9%. The committee considered different levels depending upon seed crops, food crops and forage crops. We believe that setting different levels would place a huge burden on the committee and make the guidelines for co-existence extremely confusing for both the registrar and grower. Currently, as presented during the committee meetings, independent testing companies are using the 0.9% as a level for labeling GE Free.

#5. No comment

#6.
We have spoken to the Ex. Director of the California Crop Improvement Association. This non-profit organization currently maps and certifies seed purity on an international basis. They currently have a fairly easy registration process that can be done online. Included within those discussions were what costs might be incurred if they agreed to register Lake County GE growers.
Their current software program could be modified to handle the requirements of this proposed program. Estimated costs were under $5,000.00. Other overhead costs associated with this program would be expenses associated with the Agricultural Commissioner's office working with the committee to produce the Guidelines. That would include staff time to work with the committee as, well as write up the formal guidelines. We believe those finalized guidelines would then have to be reviewed by County Council for proper legal language. Additional overhead will most likely include the cost to the county in handling any appeals submitted once the guidelines are established.
We would expect that these over head costs of this process be borne by the County as this program is supposedly for the protection for citizens of the county against the production of a perfectly legal crop.
California Crop Improvement Association or the Agricultural Commissioner would then charge a per acre fee to the registrant. The grower would be responsible for those fees.

APPENDIX 11: Stanislaus County Resolution in Support of the Use of Biotechnology in the Agricultural Industry (2005)

THE BOARD OF SUPERVISORS OF THE COUNTY OF STANISLAUS
ACTION AGENDA SUMMARY

DEPT: AGRICULTURAL ADVISORY BOARD - AG COMM **BOARD AGENDA #** B-4

Urgent ☐ **Routine** ☑ **AGENDA DATE** August 9, 2005

CEO Concurs with Recommendation **YES** ☑ **NO** ☐ **4/5 Vote Required** **YES** ☐ **NO** ☑

(Information Attached)

SUBJECT:

Approval to Adopt a Resolution in Support of the Use of Biotechnology in the Agricultural Industry in Stanislaus County - Agricultural Advisory Board

STAFF RECOMMENDATIONS:

1. Accept the Informational Presentation by the Stanislaus County Agricultural Advisory Board on the Subject of the Use of Biotechnology in the Agricultural Industry in Stanislaus County.

2. Approve a Resolution in Support of the Use of Biotechnology in the Agricultural Industry in Stanislaus County.

FISCAL IMPACT:

There are no fiscal impacts associated with this item.

BOARD ACTION AS FOLLOWS:

No. 2005-611

On motion of Supervisor DeMartini , **Seconded by Supervisor** Mayfield
and approved by the following vote,
Ayes: Supervisors: O'Brien, Mayfield, Simon, DeMartini, and Chairman Grover
Noes: Supervisors: None
Excused or Absent: Supervisors: None
Abstaining: Supervisor: None

1) X **Approved as recommended**
2) _____ **Denied**
3) _____ **Approved as amended**
4) _____ **Other:**

MOTION:

Christine Ferraro

ATTEST: CHRISTINE FERRARO TALLMAN, Clerk **File No.**

DISCUSSION:

Agriculture is the leading industry in Stanislaus County. Stanislaus County agriculture is diverse, producing over 250 different crops. In 2004, the gross agricultural production was over $1.9 billion dollars. Associated industries involved in the processing of agricultural commodities result in a "multiplier effect" so that agriculture's contribution to the local economy for the year 2004 amounted to almost $9 billion dollars.

Because of the importance of agriculture to the local economy and the community way of life in Stanislaus County, it is crucial that local growers are able to utilize a wide range of technologies available in order to produce a safe, healthy and affordable food supply. The use of biotechnology in agriculture has many benefits including: crop varieties which have been developed to ward off pests, resist particular herbicides, resist plant diseases, tolerate adverse growing conditions, as well as improving production and reducing costs.

Biotechnology in agriculture is sometimes referred to as genetic modification or genetic engineering of crops. In crop production, some major goals of genetic modification are to: reduce the need for chemical pesticides and herbicides, reduce water use, increase nutritional quality, increase food safety, improve plant quality for storage, and increase yields. Genetic modification has been in existence for thousands of years, when people first began crossbreeding plants to produce better foods and fiber. Modern genetic modification began in 1953 when scientists discovered the structure of DNA. Since then, researchers have learned how to move genetic material from one plant to another. For most crops, the seed is the delivery system through which advances in plant genetics and biotechnology are transferred into agricultural production. Genetically modified seeds can better protect crops against diseases, pests and weeds, and can generate improved products.

Biotechnology has been the subject of voter initiatives in Butte, Humboldt, Marin, and San Luis Obispo Counties in the most recent general election. The initiatives were intended to prohibit the use of biotechnology, including genetically engineered (GE) or genetically modified organisms (GMOs) and were placed on ballots by those opposed to the use of such technologies. The initiatives failed in all but Marin County. Mendocino and Trinity Counties banned the growing of genetically engineered crops on March 2, 2004 and August 3, 2004, respectively. Currently, the counties of Sonoma, Alameda, Lake, Santa Cruz, Napa, Solano, Contra Costa, Placer and Santa Barbara have activities contemplated or underway to prohibit or limit the use of biotechnology.

In order to protect agriculture and to affirm the rights of growers to choose to utilize the widest range of technologies available, several San Joaquin Valley counties have adopted resolutions to protect this right. The counties of Kern, Tulare, Merced and Fresno have all passed resolutions within the last year protecting the use of biotechnology in agriculture. It has been recognized that biotechnology can help to improve the San Joaquin Valley's air and water quality through the control of both particulate matter and ozone forming emissions through reduction of cultivated activities, and the control of sediment, nutrient and pesticide runoff into waterways through the reduction of pesticide use and tillage in the fields.

Regulatory oversight for regulating biotechnology in the United States is the responsibility of the United States Department of Agriculture, the Environmental Protection Agency and the Food and Drug Administration. New crops must meet the proper regulatory requirements before they are approved to be grown on a commercial basis and introduced in the market.

The Stanislaus County Agricultural Advisory Board recognizes that agriculture is the prime industry in Stanislaus County and plays a significant role in our economy and way of life. The Agricultural Advisory Board affirms the rights of growers to be allowed the choice of the same promising technology that is currently used by agriculturalists around the world. Therefore, the Stanislaus County Agricultural Advisory Board requests that the Stanislaus County Board of Supervisors adopt a resolution in support of the use of biotechnology in the agricultural industry in Stanislaus County.

POLICY ISSUE:

The adoption of a resolution in support of the use of biotechnology in the agricultural industry in Stanislaus County is consistent with the Board Priority to maintain a Strong Agricultural Economy/Heritage.

STAFFING IMPACT:

There are no staffing impacts associated with this item.

THE BOARD OF SUPERVISORS OF THE COUNTY OF STANISLAUS
STATE OF CALIFORNIA

Date: August 9, 2005 No. 2005-611

On motion of Supervisor DeMartini Seconded by Supervisor Mayfield
and approved by the following vote,
Ayes: Supervisors: O'Brien, Mayfield, Simon, DeMartini, and Chairman Grover
Noes: Supervisors: None
Excused or Absent: Supervisors: None
Abstaining: Supervisor: None

THE FOLLOWING RESOLUTION WAS ADOPTED: Item # B-4

RESOLUTION SUPPORTING THE USE OF BIOTECHNOLOGY IN THE AGRICULTURAL INDUSTRY IN STANISLAUS COUNTY

WHEREAS, the Stanislaus County Agricultural Advisory Board is an Advisory Board to the Stanislaus County Board of Supervisors, and

WHEREAS, the Stanislaus County Agricultural Advisory Board is comprised of agricultural leaders throughout the County and the Agricultural Advisory Board recognizes that agriculture is the number one industry in Stanislaus County, and the Agricultural Advisory Board affirms the right of farmers and ranchers to utilize the widest range of technologies available to produce a safe, healthy, abundant and affordable food supply, and that the safe, federally regulated use of biotechnology is a promising component of progressive and viable agricultural production, and

WHEREAS, the use of biotechnology in agriculture has enhanced the well-being and environmental stewardship of communities through reduced pesticide use and exposure to other environmental factors, and

WHEREAS, improvement of the San Joaquin Valley's air quality is essential and mandated by law, agricultural biotechnology can assist in the control of both particulate matter and ozone forming emissions through the use of cultivated activities, and

WHEREAS, the San Joaquin Valley's water quality is vital, agricultural biotechnology can assist in the control of sediment, nutrient and pesticide runoff into waterways through the reduction of pesticide use and tillage in the fields, and

WHEREAS, less inputs, higher crop yields, and healthier plants have and will continue to greatly enhance the vitality and viability of our agricultural economy by production choices to the farmer, and

WHEREAS, the federal government has been regulating the production and introduction of biotechnology-enhanced crops for almost two decades and those new crops go through an extensive multi-year testing process before the new crop is approved to be grown on a commercial basis, and

ATTEST: **CHRISTINE FERRARO TALLMAN, Clerk**
Stanislaus County Board of Supervisors,
State of California
Christine Ferraro

1010-56

File No.

WHEREAS, the Food and Drug Administration, the Environmental Protection Agency and the United States Department of Agriculture all must research, review and consent to the introduction of new biotechnology crops into the market, making these crops the most highly regulated and scrutinized foods in the world, and

WHEREAS, the ability to use biotechnology in agriculture is a key factor by which farmers and ranchers can stay competitive in the global marketplace, and

WHEREAS, the environmental benefits of biotechnology are important to the long-term sustainability and enhancement of our agricultural community, and

WHEREAS, the Agricultural Advisory Board approved a motion at their August 1, 2005 meeting, to support a Resolution to be presented to the Stanislaus County Board of Supervisors for their consideration to support the use of biotechnology in the agricultural industry in Stanislaus County, thus allowing farmers and ranchers the choice of the same promising technology currently used by agriculturalists around the world.

NOW, THEREFORE, BE IT RESOLVED that the Stanislaus County Board of Supervisors supports the use of biotechnology in the agricultural industry in Stanislaus County as a valuable and important tool for progressive and viable agricultural production.

APPENDIX 12: County Supervisors' Association of California Resolution in Support of Life Sciences and its Contributions to World Health and Agricultural Improvements

RESOLUTION IN SUPPORT OF LIFE SCIENCES AND ITS CONTRIBUTIONS TO WORLD HEALTH AND AGRICULTURAL IMPROVEMENTS

WHEREAS, over its history, the character of California agriculture has been in a state of perpetual transition and adjustment evolving to today's highly sophisticated, technologically advanced, management-intensive agricultural industry with a 2003 farm gate value in excess of $27 billion; and

WHEREAS, California agriculture has always been on the technological frontier in developing or modifying new technologies such as large scale mechanical technology, irrigation equipment, horticulture/plant varieties, pest control, food processing, and wine making; and

WHEREAS, the use of biotechnology in medicine and other sciences has provided unique innovations and products to the benefit of society; and

WHEREAS, biotechnology has been used in medical research for enhanced treatments for life threatening diseases, such as Alzheimer's, HIV/AIDS, diabetes, cancer and a myriad of diseases that currently have no cure; and

WHEREAS, the use of biotechnology in agriculture has enhanced the well-being and environmental stewardship of communities through reduced pesticide use, reduced soil erosion, lower water consumption and greater yield, and

WHEREAS, agricultural biotechnology can make the food we eat safer, more nutritious and free from allergens, and the technology holds the key to development of crops that can be used to create new energy sources; and

WHEREAS, the field of biotechnology has created over 230,000 high paying jobs with a $14 billion payroll in California and many businesses in several counties are on the "cutting edge" by creating a challenging business environment for start-up and established biotechnology companies; and

WHEREAS, the current and future developments of this technology in field crops represent a significant leap in addressing the hunger and nutritional needs of the world's more than 8.3 billion people by the year 2025, and

WHEREAS, biotechnology is being used to develop food and fiber crops that are salt tolerant, drought resistant, have enhanced nutritional properties, contain trans-fat free oils, and resist viral infections like Pierce's disease; and

WHEREAS, the University of California and the California State University Systems are world leaders in biotechnology research, recognizing that science is the driving force behind innovation, and that technological advancements in medicine and agriculture have been at the root of California's success, and

NOW, THEREFORE BE IT RESOLVED, the California State Association of Counties recognizes the importance of the life sciences and supports the current and future economic, medical and agricultural opportunities presented by biotechnology as regulated by the U.S. Food and Drug Administration, the Environmental Protection Agency, and the U.S. Department of Food and Agriculture.

PASSED, APPROVED AND ADOPTED at a regular adjourned meeting of the CSAC Board of Directors on June 2, 2005.

Greg Cox

Greg Cox
CSAC President