



THE HEALTH EFFECTS OF GENETICALLY ENGINEERED CROPS ON SAN LUIS OBISPO COUNTY

A Citizen Response to the
SLO Health Commission
GMO Task Force Report

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“Response to Bradford, et al.”, Dr. David Schubert, 2005

Introduction and Purpose

This citizen's report, to be submitted for the record, was drafted as an alternative to the SLO County Health Commission GMO Task Force report presented to the Health Commission in May 2006.

The goals of this report are:

- Provide the public and the Health Commission with information on the state of GMOs in SLO County and the United States.
- Inform the Health Commission to failings in our regulatory agencies that merit local action to protect our citizens.
- Inform the Health Commission of a report produced by Santa Cruz County that provides a comprehensive overview of public health concerns regarding GMOs.
- Provide responses to specific portions of the SLO County Health Commission GMO Task Force report.

Six specific recommendations are provided to the Health Commission on page 14.

The members of the public who composed this citizen's report appreciate the SLO County Health Commission delaying review of the Health Commission GMO Task Force Report to allow this response to be drafted and presented.

Health Commission GMO Task Force

In 2005, the SLO Public Health Commission voted to create a Health Commission (HC) GMO Task Force to investigate the "health considerations and implications" of GMOs. The task force was a response to Measure Q, a ballot initiative to restrict the growing of GMOs in San Luis Obispo County. Over 49,900 county citizens expressed reservations about GMOs by supporting Measure Q.

Among the goals of the HC GMO Task Force were "To gather reviewed scientific information on genetically engineered foods and crops" and generate a report "setting forth scientific information (Pro and Con) on the subject of genetically engineered foods/crops from the perspective of the health considerations and implications".

This citizen's response provides evidence that the task force failed in its goal of "setting forth scientific information (Pro and Con)" on GMOs. The HC GMO Task Force report instead was focused on information supporting the status quo – that GMOs are similar to conventional crops and do not require labeling or any mandatory testing.

In some cases, suggestions for improvement of regulations were used in the report to give the appearance of balance. However, no timeframe or likelihood of implementation was provided. In some cases these suggestions have been in existence for years and no action has been taken by US regulatory agencies.

A list of grievances with the HC GMO Task Force report and specific responses are provided in the final section of this report.

Santa Cruz GE Committee Report

Like the San Luis Obispo Health Commission, Santa Cruz County recently appointed a committee to investigate the health impacts of GMOs on Santa Cruz County citizens and agriculture. In contrast with the San Luis Obispo HC GMO task force report, the Santa Cruz GE Committee report provided a comprehensive overview of scientific and regulatory aspects of GMOs.

Participants in the generation of the Santa Cruz report included: 2 representatives from each supervisor district, the Agricultural Commissioner's office, the UC Cooperative Extension, the Public Health Commission, and County Counsel.

The committee met from August 2005 through April 2006 and released a final report in June 2006. The committee goals, meeting agendas, meeting minutes, the final report and additional resources are all available online for public review.¹

The decision by the majority of members to request a precautionary moratorium was based primarily on the following considerations:

- Inadequate regulatory monitoring and oversight of genetically engineered crops at the federal and state level to ensure public health and environmental safety. A recent audit conducted by the USDA's Inspector General, found that the Agency is not living up to its own protocols for GE crop regulation. The report found that the USDA did not know the location of many of the GE test sites being used; some GE test crops, including drug-containing crops, remained in the test fields and contaminated subsequent harvests; and some crops not approved for human consumption have found their way into the food supply.
- Health testing of the effects of exposure to GE organisms is not required by any government agency. The lack of comprehensive safety testing leaves a potentially dangerous scientific void in the knowledge available about the short and long-term health effects of GE foods.
- 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.

The Santa Cruz GE Committee report is a consensus document and participants agreed on the content. However, a minority of members dissented with the recommendation from the Santa Cruz GE Committee to institute a moratorium.

Each SLO County Health Commissioner and SLO County Supervisor has received a complete copy of the Santa Cruz GE Committee report for reference.

¹ <http://www.santacruzhealth.org/ge/>

Genetic Engineering Overview

Genetically Engineered versus Traditional Breeding

Genetic Engineering (GE) for the purposes of this report includes crops produced by taking genes from one species and inserting them into another using recombinant DNA (rDNA) technology. Genetic Engineering is also referred to as transgenic or GMO. These terms are used interchangeably in this report.

Besides the gene for the desired traits, genetic engineering inserts “markers” which are used to determine if the desired trait was successfully inserted and “promoters” that force the desired traits to express their protein(s) at all times.

FDA scientists determined that GMO crops carry unique risks and should be regulated differently

Genetic Engineering is not the same as conventional breeding and not something that has been occurring for thousands of years. Logically, when regulations were being developed for GMO crops in the early 90's FDA scientists determined that GMO crops carry unique risks and should be regulated differently.² The political appointee in charge of biotech policy, Michael Taylor overruled the FDA

scientists. Michael Taylor worked for the Monsanto Corporation as a lawyer before being appointed to the FDA. Taylor went on to become an administrator at the USDA in charge of food safety and biotechnology, and then became a vice-president at Monsanto.

Historical FDA documents show us that the equating of genetic engineering with traditional breeding was founded in politics not science.

Unfortunately, FDA scientific conclusions are still being manipulated. A July 2006 Union of Concerned Scientists (UCS) survey found that over 61% of the nearly 1,000 FDA scientists who responded knew of cases where “... FDA political appointees have inappropriately injected themselves into FDA determinations or actions” and 60% knew of cases “where commercial interests have inappropriately induced or attempted to induce the reversal, withdrawal or modification of FDA determinations or actions.”³

Unintended Effects of Genetic Engineering

Advocates of genetic engineering often assert that GMO crops are “similar to” or even “are more precise”⁴ than traditionally bred crops. The implication is that they carry the same or even less risk. However, a National Academy of Sciences report in 2004 concluded that genetically engineered foods have a higher likelihood of unintended effects over traditional breeding techniques.

² Refer to the appendix for Dr. Linda Kahl's memorandum obtained through a Freedom of Information Act lawsuit against the FDA in 1999.

³ See Appendix for UCS summary of survey

⁴ “To dismiss completely the idea that biotechnology is very similar to classical plant breeding (except that it is more precise) contributes to the deconstruction of Schubert's conclusions by Beachy et al (2002) and Avery (2002).” – SLO GMO Task Force Report, p17

The following figure graphically illustrates relative ranges of unintended effects as determined by the NAS. The major GMO crops on the market – corn, cotton, soybeans, and canola – fall into the 2nd and 3rd highest categories for risk of “unintended effects”.

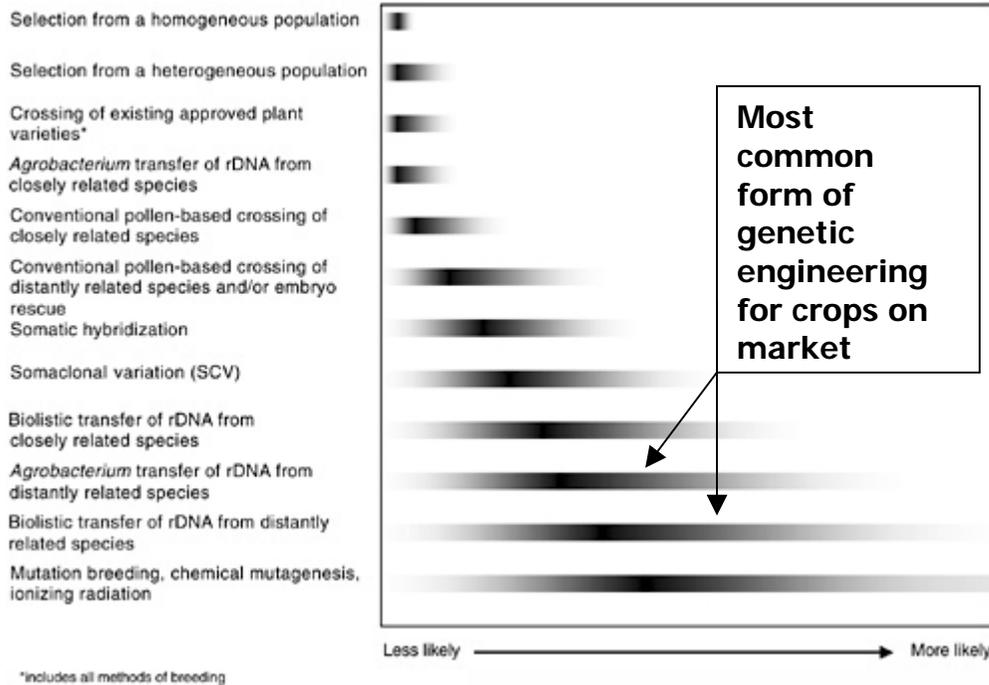


FIGURE 1: NATIONAL ACADEMY OF SCIENCES UNINTENDED EFFECTS

Because GMO crops entail greater risk, it follows that they should be tested thoroughly before being released into the open air. Unlike a failure of an automobile, bridge, or other mechanical device, GMO seeds and pollen are self-replicating and will be virtually impossible to eradicate once introduced in nature.

The peer reviewed article “Safety Testing and Regulation of Genetically Engineered Foods” by William Freese and David Schubert mentions a few examples of unintended effects found in existing crops:⁵

Excess lignin production in *Bt* corn (Saxena and Stotzky, 2001), reduced levels of certain phytoestrogens in glyphosate-tolerant soybeans (Lappe *et al.*, 1998) and unpredicted changes in the small molecule metabolism of GE potatoes (Roessner *et al.*, 2001) are three of many examples of unintended effects in GE crops (see also Kuiper *et al.*, 2001, Haslberger, 2003).

⁵ See section on Pleiotropic Effects (Schubert) for additional details

Dr. Schubert, in a correspondence responding to criticisms of this paper, had this to say about those scientists attempting to equate genetic engineering and natural breeding:

... plant biotechnology is attempting to change the technical definitions of genetics for the purpose of self-promotion. They state that "conventional breeding is based on essentially random induction or assembly of mutations", followed by "imprecise natural recombinations between genomes". Thus, they are equating recombination with mutagenesis, and so, by extension, GE with natural breeding. **This is not only scientifically incorrect but also exceptionally deceptive.**

State of GMO Crops

Since 1986, the USDA has been informed of over 10,600 different GMO test crops for over 49,300 different field sites.⁶ Test plots may contain crops for food, pharmaceutical or industrial purposes. Nearly 99% of test crops are planted in open air after a notification letter is sent to the USDA⁷. There is no required testing for either food contamination or environmental safety.

Grapes, strawberries, lettuce, broccoli, alfalfa, peppers and dozens of other crops are on the list of test plots planted in California.⁸

The Animal and Plant Health Inspection Service (APHIS), tasked with regulating test plots, was audited in 2005⁹. The audit revealed major failures in the monitoring of GMO test plots.

Two of the more troubling conclusions:¹⁰

"Of primary concern, the precise locations of all GE field test sites planted in the United States are not always known"

"At the conclusion of the field test, APHIS does not require permit holders to report on 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"

While GMO advocates may claim that APHIS is now "implementing changes", they have refused to make some:

Lastly, APHIS did not agree with developing policy guidelines for restricting public access to edible regulated crops when conducting field tests and with

⁶ Audit Report: Animal and Plant Health Inspection Service Controls Over Issuance of Genetically Engineered Organism Release Permits, December 2005 (Executive Summary attached)

⁷ 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."

⁸ See Appendix 4 in Santa Cruz GE Committee Report (p46) for a full list of test crops

⁹ APHIS Controls Over Issuance of Genetically Engineered Organism Release Permits (Audit Report 50601-8-Te)

¹⁰ Refer to the Santa Cruz GE Report section entitled "Regulatory Frameworks" for more details.

developing policies and procedures for selecting specific field test sites for inspection based on risk.

Finally, the promises of APHIS have fallen short in the past:

Although APHIS agreed to improve its tracking of inspection reports following an Office of Inspector General (OIG) audit more than 10 years ago, the agency continued to lack an effective, comprehensive management information system to account for all inspections and their outcomes. In fact, we found 11 violations that were not recorded in BRS' compliance infractions database at the time of our audit, even though they were reported to BRS or could have been identified from information BRS already had. APHIS took administrative action on only 1 of those 11 violations.¹¹



FIGURE 2: TOTAL NUMBER OF ISSUED OR ACKNOWLEDGED FIELD TEST SITES

The audit makes it clear that APHIS is not guarding the public trust and that nobody (even APHIS) can currently speak with authority regarding the state of GMOs in the United States or San Luis Obispo County.

Avila Valley Barn is the only known current grower and seller of GMO crops in the County and that is only because the owner disclosed this to SLO GE Free in 2004. Cal Poly disclosed growing GMO corn in 2004 as part of a marketing study.

GMO Peer-Reviewed Science

Health and environmental impact studies of GM crops have been rarely subjected to peer review. As of 2003, there were 10 in-vivo published feeding studies dealing with health implications associated with GMO food crops.¹² Five of the studies were

¹¹APHIS Controls Over Issuance of Genetically Engineered Organism Release Permits (Audit Report 50601-8-Te)

¹²"In Vivo Studies On Possible Health Consequences Of Genetically Modified Food And Feed—With Particular Regard To Ingredients Consisting Of Genetically Modified Plant Materials", Ian F. Pryme and Rolf Lembcke

corporate funded (fully or partially) and found no problems. The other five all raised some concerns.

Although GMO corporations have reported to the FDA that they are performing tests, the actual test data is typically not available for public review. There are only two GMO crops - of the thousands that have been planted - where full corporate test data is available, the FlavrSavr tomato and MON863 corn.

The first crop to be approved by the FDA, the FlavrSavr tomato, was released despite studies showing that the GMO tomato caused stomach lesions. FDA scientists who reviewed the study requested additional testing be performed but this was never provided.

In 2005, Monsanto was forced to release an internal feeding study of MON863 corn. After review, France's expert Commission du Genie Biomoleculaire (CGB) recommended against MON863 approval because of human safety concerns. Rats fed the corn for 12 weeks developed internal abnormalities, had smaller kidneys and showed worrying changes in blood composition including:

- Increased white blood cells in the males
- Reduced immature red blood cells (which carry iron and oxygen) in the females;
- A significant increase in blood sugar in the females;
- Other physical irregularities of the males, such as inflammation of the kidneys.

A molecular geneticist at Guy's Hospital Medical School in London, Dr Michael Antoniou, stated the findings were "very worrying from a medical point of view. I have been amazed at the number of significant differences they found [in the rat experiment]."

MON863 is already approved in the United States. These experiments were not necessary for US approval.

Labeling of GMO Foods

Although dozens of countries label GMO foods, the United States, along with countries like Benin, Zimbabwe, and Angola, does not.¹³ Ample evidence shows that the American people overwhelmingly want GMO food to be labeled. However, like the food industry that opposed any food labeling for decades, GMO producers are adamantly opposed to labeling GMO content. GMO producers realize that consumers would likely purchase a product that didn't contain GMOs if given the choice.

GMO crops have been released in large quantities for roughly the past 10 years. Over this time, Type 2 diabetes, asthma, allergies, and stomach conditions such as acid reflux have increased. Is there possibly a connection between GMO crops on the market and these problems? Or is it just a coincidence?

If the GMO food industry can't survive consumer choice, then those foods shouldn't be sitting on the shelves of American grocery stores, and no scientist, corporation, political entity or university should stand in the way of that democratic process.

¹³ Refer to the Santa Cruz GE Committee report, Appendix 5, p57 for labeling details

Because there has been no labeling of GMO ingredients, the public does not know what they are eating and linking diets rich in GMO ingredients to these diseases is impossible to verify scientifically. More importantly, if it were ever to be shown conclusively that GMO foods caused these diseases, the producers of these foods could not be held liable because it would be impossible to trace who has eaten what.

Consumers have the right to a choice in what they eat and feed their families. Consumers have the right to eat foods that have not been contaminated with GMO seeds or pollen from test crops.

Labeling is the immediate and democratic answer to the questions and controversies over GMOs. Let the public know what they are eating, then let them choose. If the GMO food industry can't survive consumer choice, then those foods should not be sitting on the shelves of American grocery stores, and no scientist, corporation, political entity or university should stand in the way of that democratic process.

Regulation of GMO Foods

The FDA does not require any testing of GMO foods. The FDA offers a voluntary consultation process that allows a corporation to present results of internal testing to the FDA. However, the FDA does NOT take a position on the safety of the food. Instead, at the end of the consultation process, the FDA sends a letter to the company stating that it is the company's responsibility to make sure the product is safe.¹⁴

The goal of the regulatory process is to treat GMO foods just like conventional foods despite the fact that they are unique enough to patent.

Bt crops are an example of the regulatory structures in place – and how they have been adapted to circumvent the need for both scientific testing and labeling of GMOs. Bt crops have the Bt protein – an organic pesticide – inserted into every cell of the plant. Cells of the plant express the Bt pesticide at all times. The plant is the pesticide!

EPA: Even though the FDA has jurisdiction over food additives, Bt is a pesticide so they don't regulate it. That's the responsibility of the EPA. However, the EPA works from the assumption that if the original crop is safe and the Bt protein added to it is safe, then the whole Bt crop is presumed to be safe.

EPA end result: No food safety testing is required.

FDA: Even though Bt is an organic pesticide and quite safe, the product is still labeled with warnings like "avoid inhaling the spray or getting it in an open wound". So, why isn't the food labeled? The FDA has sole jurisdiction over the labeling of plant foods, and the FDA has ruled that biotech foods need be labeled only if they contain known allergens or have otherwise been "materially" changed. Isn't adding Bt materially changing a plant? Yes, but the FDA's Food, Drug and Cosmetic Act specifically bars the FDA from including any information about pesticides on its food labels.

FDA end result: No labeling required.

¹⁴ See Appendix for actual FDA letter to GMO producer

Genetic Contamination Events

Contamination events fall into three major categories.

1. Contamination of seed stocks with released GMO seeds.
2. Contamination of crops from GMO seeds and pollen from open-air field trials.
3. Contamination of food crops with seeds and pollen from GMO pharmaceutical and industrial crops.

The *public* is aware of at least a dozen major contamination events that have occurred since the introduction of GMOs. The USDA has attempted to cover up contamination incidents in the past.¹⁵

The Santa Cruz GE Committee report provided details of all the known contamination events starting on page 12 of that report.

Ethics and GMOs

Ethical considerations are essential to evaluating the safety of GMO foods. This is because the entire burden for safety is placed on the corporations creating the GMO.

If corporations producing GMO crops have a demonstrated history of distorting the truth for financial gain, the public would be naïve to blindly trust them with our safety.

Ethical issues worthy of investigation include, among other things, corporate ownership of seeds, massive conflicts of interest with government and educational institutions¹⁶ and bribery of foreign governments¹⁷.

The Santa Cruz GE Committee report provides additional discussion on the social implications of GMOs.

Alternatives to GMOs

For consumers, the alternative to GMOs is certified organic agriculture. Organic agriculture prohibits the use of GMO seeds. Since the United States does not require labeling of GMOs, this is the best way to avoid them.

From a science perspective, marker assisted selection (MAS), which uses genetic technology in combination with traditional breeding, is a growing alternative. MAS allows breeders to identify desired traits in a crop or related species and use traditional breeding techniques to amplify or move those traits into the target crop.

While MAS cannot move genes from incompatible species, geneticists are increasingly finding that traits previously thought unavailable in a plant are present but just not being expressed.

¹⁵ The USDA was made aware of Bt10 contamination in November 2004 but only released details to the public months later after an employee leaked the information to the press.

¹⁶ See Appendix for USDA, Inc. Executive Summary Excerpt from report published in 2004

¹⁷ Monsanto admitted to bribing foreign governments to eliminate GMO bio-safety protocols and was fined \$1,000,000 (0.018% of their net sales for 2004) (<http://tinyurl.com/oynk>)

For example, the discovery of the vitamin A pre-cursor (beta carotene) gene in rice caused a scientist from the GMO producer Syngenta to state: "All the genes are present in rice. One could make a non-GM Vitamin-A Rice simply by studying those genes in a more focused way."

Two major problems recently solved with genetics but without the need for transgenic science are the accelerated breeding of a Pierce's Disease resistant grape vine¹⁸ and discovery of a soybean free of the most common allergenic protein.

¹⁸ "Marker-Assisted Selection For Resistance To Xylella Fastidiosa: Accelerated Breeding Of Pierce's Disease Resistant Grapes", A. Walker, A. Krivanek, and S. Riaz, University of California Davis

Recommendations to the SLO Health Commission

SLO County citizens have the right to know to what unapproved, experimental crops and pollen they are being exposed. SLO County citizens have the right to decide what they eat and feed their families. These are reasonable requests.

To secure SLO County citizens and land from exposure to GMO crops and pollen – in particular from test plots, SLO GE Free recommends that the Health Commission take the following actions:

1. The Health Commission should submit a Freedom of Information Act (FOIA) request to determine the location of all genetically engineered test plots in SLO County from the USDA (APHIS). A draft FOIA request is provided in the Appendix.
2. The Health Commission should recommend that the Agricultural Commissioner institute a mandatory registration program for both test plots and approved genetically engineered crops.
3. The Health Commission should recommend a precautionary approach to the adoption of genetically engineered crops in San Luis Obispo County to the Board of Supervisors, similar to the one adopted by the Santa Cruz Board of Supervisors.
4. The Health Commission should send a letter of support for the Genetically Engineered Food Right to Know Act in Congress to our Representatives and send letters to the local Farmer's Market boards encouraging vendors to label GMO produce.
5. The Health Commission should take a stance supporting organic agriculture as in the best interest of our citizens, land, air and water.
6. The Health Commission should disregard the HC GMO Task Force report based on a failure to fulfill the stated goals.

The following questions, excerpted from the Santa Cruz GE Committee goals, should be answered in order for the SLO County Health Commission to make an informed decision on how to deal with GMO crops in the County:

- What peer-reviewed, independent, multi-generational feeding studies have been conducted on GMO foods?
- What is occurring now and what is the potential for GM crops and crop applications in the United States, California, and [SLO] County?
- What kinds of GM research are being conducted in the county that has the potential to contaminate nearby crops and neighborhoods?
- Are there field trials of pharmaceutical or industrial 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?
- What notification procedures exist to inform nearby residents and farmers of the intent to plant a GM commercial or "test" crop?

Health Commission GMO Task Force Response

Responses to portions of the HC GMO Task Force report are provided in the following pages. Before reading these responses, Health Commissioners should read the Santa Cruz GE Committee report. The Santa Cruz report provides a comprehensive analysis of actual and potential health implications of GMOs and provides additional background for these responses.

HC GMO Task Force Composition

Immediately after its formation, serious questions were raised about the composition of the HC GMO Task Force. Calls by both those supporting and opposing Measure Q to create a task force with equal representation were ignored. Instead:

- The selection process excluded persons openly expressing concern with GMOs
- The selection process seated 3 pro-GMO activists. These 3 took the lead in composing 3 of the 4 main sections of the HC GMO Task Force Report.
- Two task force members have direct financial ties to the GMO industry¹⁹.
- The criterion for member selection has never been revealed even though numerous requests for this information have been made.

As feared by many members of the public, a task force led solely by people with vested interests in the success of GMOs proved incapable of generating a report that accurately represented the science, regulatory, and ethical facts surrounding GMOs.

Unfortunately, rather than addressing the concerns of over 49,900 county citizens who voted to prevent the growing of GMOs, this task force report will have the effect of justifying and expanding those concerns.

HC GMO Task Force Report Overview

Due to the following inadequacies, the HC GMO Task Force did not achieve the goals set forth by the Health Commission:

1. No discussion of available short-term or long-term peer-reviewed animal feeding studies – or lack thereof – for GMO foods on the market. This would be an important part of any report dealing with the Public Health concerns of growing and consuming these foods.
2. No mention of a 2005 USDA APHIS audit criticizing the agency for massive failures in the oversight of open-air GMO test plots
3. No discussion of open-air test plots of food, pharmaceutical and industrial crops.

¹⁹ Scott Steinmaus was Project Director for a grant that received \$40,000 from Monsanto and Dow (<http://tinyurl.com/fomjl>). Michael Broadhurst was International R&D Sector Leader for Zeneca Ag Products. Zeneca (now owned by Syngenta) is a producer of GMO crops and owner of Vitamin-A "Golden Rice" (<http://tinyurl.com/febzr>)

4. No mention of more than a dozen GMO contamination incidents that have occurred – most of which have involved test crops.
5. Failure to include a peer-reviewed paper presented by Nancy Reinstein, PhD, RD (Freese and Schubert 2004) that highlighted severe deficiencies in regulatory guidelines related to GMOs.
6. No mention of evidence that vindicated Dr. Arpad Pusztai. The task force report also mentions personal communications with Dr. Pusztai that never took place.
7. No in-depth ethical analysis of GMO crops, despite the fact that a “bio-ethicist” was intentionally added for this purpose.
8. No discussion on the benefits of labeling GMO foods including traceability, epidemiological studies, and consumer choice.
9. No mention that the NAS report concluded that GMO crops carried a higher risk of unintended effects over traditional breeding. The opposite message was conveyed – that GMO is similar to traditional breeding.
10. No environmental assessment of how GMOs will affect insect (Bt crops) and weed (Roundup-Ready) populations.
11. No mention of how increased Roundup herbicide use due to Roundup Ready crops may be harming our citizens and the environment.²⁰
12. No discussion of the MON863 corn study released in 2005 by Monsanto, only the second publicly released corporate funded animal feeding study for a GMO crop.
13. Failure to include specific corrections to the two report sections (Nutrition and FDA Regulation) provided to the public before the May 8th, 2006 meeting. These corrections included:
 - The elimination of a statement under Nutrition section that “Furthermore, a problem such as lesions or bleeding due to ingestion of a GE crop will prevent that crop from ever entering the commercial market.”²¹
 - The addition of the fact that the FDA is ignoring the law regarding GRAS.

Evidence Rather than Prediction

Objective 4 of the GMO Task Force was: “Providing balanced reports [...] based in evidence, rather than prediction.”

The HC Task Force report in several instances dismisses predictions of potential harm with GMOs but does not hesitate to make predictions supportive of GMOs. The citations below include the page number in the report.

| If the transgene disrupts important genes the cells will not survive. (p16)

²⁰ “The Impact Of Insecticides And Herbicides On The Biodiversity And Productivity Of Aquatic Communities”, Dr. Rick Relyea, <http://www.pitt.edu/~relyea/Roundup.html>

²¹ See FlavrSavr Tomato Approval section in the Appendix

With no definition of “important”, this statement is meaningless. This statement implies that the plant will catch any problems missed by the biotechnologist and is not a scientifically valid point. If an affected gene increases the expression of a toxin – or expresses a toxin not previously present in the plant – the cell could easily survive.

Secondly, biotech crops are subjected to a battery of tests designed to detect unpredicted effects from many kinds of sources including alternative splicing of mRNAs and post-translational processing of target proteins and *any other unintended impacts* [emphasis added] of on plant metabolism that may occur. (p17)

This statement goes against the premise that “one cannot assure absolute safety” in order to support GMOs when it states that tests will find “any other unintended impacts on plant metabolism that may occur”.

Recent publications emphasize that horizontal gene transfer from transgenic plants to soil bacteria should be monitored (Nielsen and Townsend 2004) even though it is unlikely due to significant biological hurdles (Davison, 2004). (p18)

Saying something is “unlikely” is just as speculative as saying it is “possible” given that thousands of crops are planted on millions of acres.

Furthermore, a problem such as lesions or bleeding due to ingestion of a GE crop will prevent that crop from ever entering the commercial market. Thus, one could argue that appropriate testing methods currently in use may be adequate to identify problems. (p22)

This reference was meant to apply to Dr. Pusztai’s research. In this case, Pusztai was performing research never required by regulatory agencies nor performed (to the public’s knowledge) by the GMO producers on any crop.

That said this statement is factually incorrect. The FlavrSavr tomato, the first GMO crop released, caused stomach lesions in rats and was still approved for release. See Appendix for the actual FDA documentation.

Mr. Mark Phillips pointed this out on a draft and requested this be corrected in the final report. The task force member in charge of this section agreed but failed to make any change.

However the consumer benefits because the crops can be produced more economically. As a consequence, the produce will be less costly. (p22)

There is no evidence cited that corn, cotton, or soybean costs have decreased since the introduction of GMOs. Taxpayers already heavily subsidize all three crops and prices have nothing to do with production costs. If anything, the loss of export markets to countries that don’t want GMO corn have likely increased subsidies. That’s why many people refer to the Farm Subsidy Bill as the GMO Subsidy Bill.

A number of new crops with potential to directly benefit the consumer will soon be introduced or are in research stages. (p22)

No list of crops, traits, or timeframes was provided for reference. The GMO industry has been promising consumer oriented crops for decades with no demonstrated results.

FDA Regulation Section Overview

Although this section was the most detailed portion of the report, the FDA position on GMOs can be summarized with a single sentence:

The FDA requires no testing prior to the release of a GMO crop.

The FDA documentation cited regarding “voluntary consultations” leaves many scientists concerned that the FDA is not acting in the public interest regarding the regulation of genetically engineered crops.²²

The following conflicting statements may best explain public unease regarding GMOs. Monsanto controls nearly 90% of the global GMO seed market.

"Monsanto should not have to vouchsafe the safety of biotech food ... Our interest is in selling as much of it as possible"
Phil Angell, Monsanto

"Monsanto should not have to vouchsafe the safety of biotech food... Our interest is in selling as much of it as possible. Assuring its safety is the FDA's job." -- Phil Angell, Director of Corporate Communications, Monsanto, quoted in the New York Times Magazine, October 25, 1998

"Ultimately, it is the food producer who is responsible for assuring safety." -- FDA, "Statement of Policy: Foods Derived from New Plant Varieties", (GMO Policy), Federal Register, Vol. 57, No. 104 (1992), p. 22991

FDA Regulation: Generally Recognized as Safe (GRAS)

The FDA is violating the law regarding GRAS applications. Existing law states the FDA shall “affirm” each GRAS application. However, the GRAS process is now “notification only”. The GMO Task Force refused to add this citation to the final report.

Having a law on the books that isn't enforced is a win-win for the GMO industry and gives the illusion of security for the public. The GMO producer can claim “rigorous review by the FDA” knowing full well that such a review never takes place.

According to the FDA website:²³

Does FDA currently have a program to affirm that one or more uses of a food substance are GRAS?

In a proposed rule that FDA published in 1997 (62 Fed. Reg. 18938; April 17, 1997), FDA explained why the agency could no longer devote resources to the voluntary GRAS affirmation petition process that is described in 21 CFR 170.35(c) and proposed to abolish that process and replace it with a notification procedure.

²² “Safety Testing and Regulation of Genetically Engineered Foods” by William Freese and David Schubert

²³ <http://www.cfsan.fda.gov/%7Edms/grasguid.html>

[...] **However, at this time FDA is not committing resources to the review of GRAS affirmation petitions.** (emphasis added)

FDA Regulation: Substantial Equivalence

The Task Force report states that:

"the concept of 'substantial equivalence,' which was introduced by the Organization for Economic Cooperation and Development in 1993... is widely regarded as a sound basis for safeguarding the quality and safety of biotech foods..."

In fact, the OECD has concluded the following:

"There is a need to review the principle of substantial equivalence. The OECD has carried out an ongoing review of the concept over its five years of use, but the conference was of the view that a more fundamental reassessment is necessary. The means for carrying out a transparent review – which should acknowledge the need to include the various interest groups – should be worked out between the various international bodies active in the field..."

"GENETICALLY MODIFIED FOODS: Widening the Debate on Health and Safety,"
The OECD Edinburgh Conference on the Scientific and Health Aspects of Genetically Modified Foods (2000)

The Task Force Report states:

"Consumer and advocacy groups feel strongly that the above definitions DO NOT represent the possibility of safety problems with genes inserted into DNA that is not consistent with the original organism."

"There is a profound difference between the types of unexpected effects from traditional breeding and genetic engineering"

**- Dr. Louis Pribyl
FDA microbiologist**

In fact, it is not just "consumer and advocacy groups" who "feel strongly" about the use of substantial equivalence to evaluate the safety of genetically modified organisms. As mentioned earlier, the FDA's own scientists questioned this policy.

On substantial equivalence, FDA microbiologist Dr. Louis Pribyl stated: "There is a profound difference between the types of unexpected effects from traditional breeding and genetic engineering which is just glanced over in this document."²⁴

Dr. E.J. Matthews of the FDA's Toxicology Group warned that "genetically modified plants could ... contain unexpected high concentrations of plant toxicants," and cautioned that some of these toxicants could be unexpected and could "be uniquely different chemicals that are usually expressed in unrelated plants."

²⁴ See Appendix for actual FDA memo

The numerous internal FDA critiques of the proposed policy were summed up by Dr. Linda Kahl, FDA compliance officer, who protested that the agency was “trying to fit a square peg into a round hole [by] trying to force an ultimate conclusion that there is no difference between foods modified by genetic engineering and foods modified by traditional breeding practices.”²⁵

"The processes of genetic engineering and traditional breeding are different," she declared, "and according to the technical experts in the agency, they lead to different risks."

The documents also uncovered an internal view from the Environmental Protection Agency:

"This technology is being promoted, in the face of concerns by respectable scientists and in the face of data to the contrary, by the very agencies which are supposed to be protecting human health and the environment. The bottom line in my view is that we are confronted with the most powerful technology the world has ever known, and it is being rapidly deployed with almost no thought whatsoever to its consequences."

Dr. Suzanne Wuerthele, US Environmental Protection Agency toxicologist

"The processes of genetic engineering and traditional breeding are different and according to the technical experts in the agency, they lead to different risks."

**- Dr. Linda Kahl
FDA scientist**

We presume the Task Force did not include this information in its report, as it conflicts with its bias of framing concerns about GMO's as emanating solely from “consumer and advocacy groups,” whereas it is always “scientists and federal regulatory officials” cited on the side of GM-foods-are-safe. This is a constant throughout the report.

FDA Regulation: The Precautionary Principle

The Precautionary Principle is a way of making decisions that protect the environment and human health better than the “risk assessment” model. If a practice poses threats to human health or serious environmental damage, the Precautionary Principle uses the best available science to identify cost-effective measures that would prevent harm. In the case of genetically modified organisms, this would likely include labeling and monitoring, and bar open-air cultivation.

Contrary to the Precautionary Principle, the risk assessment approach would, for example, approve the use of a pesticide until we discover direct proof that it's bad for the environment (see: DDT), or rule that it's okay to use arsenic pressure-treated wood for playground equipment because only 1 child in 10,000 will eventually develop cancer as a result.

The Task Force Report's extremely cursory discussion of the Precautionary Principle conflates it with long-term health studies, which it then strongly suggests are infeasible, and gives the last word to the biotech industry, which “has concerns that the essence of the ‘precautionary principle’ is misused and its application by advocates is to treat a lack of evidence as evidence against bringing out new GM food.”

²⁵ See appendix for actual FDA memo

The Task Force Report tacitly accepts the risk assessment model and the authors are so heavily yoked to it they are unable to step away and adequately evaluate the alternative model, and even more critically, do not attempt a comparison of the precautionary vs. risk assessment approach.

The Task Force Report's statement that it is:

"generally agreed that long-term monitoring of the human health risks of GM food through epidemiological studies is not necessary because there is no scientific evidence suggesting any long-term harm from these foods,"

This unwittingly exposes the essential flaw in the risk assessment model, which appears here as a snake eating its tail (there's no need to study long-term harm because there is no evidence of long-term harm, because there have been no studies to assess long-term harm, because...) and is an indication of just how problematic is the Task Force's acceptance of the risk assessment model and its treatment of the precautionary principle.

For a more balanced view, we recommend Michael Pollan, Knight Professor of Science and Environmental Journalism at UC Berkeley:

"The problem with risk analysis, which came out of the world of engineering and caught on during the late 70's, is that it hasn't done a very good job predicting the ecological and health effects of many new technologies. It is very good at measuring what we can know - say, the weight a suspension bridge can bear - but it has trouble calculating subtler, less quantifiable risks. (The effect of certain neurotoxins on a child's neurological development, for example, appears to have more to do with the timing of exposure than with the amount.) Whatever can't be quantified falls out of the risk analyst's equations, and so in the absence of proven, measurable harms, technologies are simply allowed to go forward.

"In Europe, a different approach has taken hold. When Germany, for example, discovered in the 70's that its beloved forests were suddenly dying, there was not yet scientific proof that acid rain was the culprit. But the government acted to slash power-plant emissions anyway, citing the principle of Vorsorge, or "**forecaring**." Soon, Vorsorgeprinzip - the forecaring, or precautionary, principle - became an axiom in German environmental law. Even in the face of scientific uncertainty, the principle states, actions should be taken to prevent harms to the environment and public health.

"The problem with risk analysis [...] is that it hasn't done a very good job predicting the ecological and health effects of many new technologies"
- Michael Pollan

(- "The Year In Ideas: A to Z; Precautionary Principle," December 9, 2001)

And there is this succinct statement from the British Medical Association:

"The threat of new allergic reactions and the unknown hazards of transgenic DNA mean that on health grounds alone the impact of GMOs must be fully assessed before they are released. The environmental implications and the long term effects on human health cannot be safely predicted at this stage and caution must therefore prevail."

On June 27, 2006, the Mendocino County Board of Supervisors adopted the [Mendocino County Precautionary Principle Policy](#). A copy of this policy is included in the appendix.

It, too, provides an explanation of the Precautionary Principle superior to that provided by the HC GMO Task Force and provides an excellent model for San Luis Obispo County.

Some opponents of the precautionary principal, acknowledging that no product can be proven to be completely safe, have argued that it is an unreasonable hurdle. The Santa Cruz GE Committee Report deals with this objection by clearly stating 5 concrete steps that must be in place in order to end the moratorium.²⁶

Distrust of Transgenic Science

The GMO Task Force called this section "*General* Distrust of Transgenic Science" (emphasis added), possibly implying that no real concrete information was supplied by the public. In reality, the public provided specific, scientific papers raising serious theoretical and demonstrated concerns about transgenic science. For the most part this information was ignored.

Three specific items are rebutted in the following sections.

Pustzai Research Response

In 1995, Dr. Pusztai and his colleagues at the Rowett Institute won a contract to create the model for testing GMO foods that was to be used by Britain and likely the entire EU. The test design won out over 27 other contenders after thorough scientific review.

In 1998, as part of this research, Dr. Pusztai conducted a feeding study on a transgenic potato engineered to contain snowdrop lectin. The lectin would enable the plant to ward off pests. During the study, Dr. Pusztai found that rats fed the GMO potato suffered serious problems²⁷ while the rats fed non-GMO potato with the lectin sprinkled on top did not. Dr. Pusztai, knowing the GMO foods already on the market had not undergone this level of scrutiny before being release, decided to go public with his findings prior to undergoing peer review.

For this, he was fired and gagged by his employer, forced into retirement, and has been continuously attacked by pro-GMO activists ever since.

The GMO task force report participated in this attack. In a systematic way, the authors of the GMO Task Force report ignored evidence that provided any vindication for Dr. Pusztai's research.

²⁶ Please refer to the Santa Cruz GE Report, Conditions that Must be Met to Lift the Precautionary Moratorium on GE Crops, p7

²⁷ Included less developed brains, livers, testicles and enlarged pancreas and intestine.

Mark Phillips provided dozens of documents to the GMO task force regarding Dr. Pusztai's experiments. In addition, Mr. Phillips had personal communications with Dr. Pusztai in an attempt to answer the task force's questions regarding the study. Dr. Pusztai offered to communicate directly with task force members but the task force never responded to the offer.

The following information, all provided to the task force by the public, was not included in the report:

A review of Dr. Pusztai's research signed by 23 independent scientists from 13 countries found the data was "sufficient to vindicate entirely Dr. Pusztai's statements".

1. A review of Dr. Pusztai's research signed by 23 independent scientists from 13 countries. Among other findings it stated that the research "showed very clearly that the transgenic GNA-potato had significant effects on immune function and this alone is sufficient to vindicate entirely Dr. Pusztai's statements".²⁸
2. Dr. Pusztai's response to the blank vector argument published in the Lancet Vol 354, page 1726-1727, 13-Nov-1999²⁹
3. Dr. Pusztai's response to the "archaic formalin fixation ... methods" published in the Lancet³⁰
4. A response from the editors of the Lancet Journal to the British Royal Society statement that "no meaningful conclusion could be reached from Ewen and Pusztai's (1999) experiments". They called the statement a "gesture of breathtaking impertinence".³¹
5. Failure to include that Pusztai, prior to the experiment, fed rats 800 times the dose of lectin compared to what the GMO crop produced with no ill effects on rats. This eliminates the possibility that the lectin itself was the problem as suggested by the HC GMO task force report.³²

Finally, the task force authors imply that they personally communicated with Dr. Pusztai.

"In an attempt to rectify this issue members of this panel (Steinmaus and Broadhurst) attempted to assess Pusztai's claims directly. Pusztai's response to the question 'how did you transform the GM potatoes used in your experiments' Pusztai replied, '...internodal stem fragment propagation...(Steinmaus, pers. comm..). There were no additional exchanges." (p16)

²⁸ See Appendix for Pusztai Research Responses

²⁹ See Appendix for Pusztai Research Responses

³⁰ See Appendix for Pusztai Research Responses

³¹ See Appendix for Pusztai Research Responses

³² "... Fenton et al. (1999) proclaims that snowdrop lectin (GNA), the same protein that Ewen and Pusztai reported on, shows a propensity to bind to human white blood cells thus calling for a greater understanding of this source of lectin before placing it into the human food chain." GMO Task Force Report, p16

However, the task force never communicated with Dr. Pusztai.³³ As mentioned earlier, the task force failed to respond to an offer from Dr. Pusztai to directly answer questions about his experiment.

The question of why the task force would imply that a personal communication took place - when clearly one did not - will hopefully be answered by the task force to the full Health Commission.

Pleiotropic Effects (Schubert)

Nancy Reinstein, PhD, RD, presented a peer-reviewed paper to the GMO Task Force entitled "Safety Testing and Regulation of Genetically Engineered Foods" by William Freese and David Schubert, published in *Biotechnology and Genetic Engineering Reviews* V21, Nov 2004. A copy of the presentation was provided to the Task Force, and a copy was provided to the Health Commission.

The following is an excerpt from the introduction of the paper:

Here, we will undertake a science-based critique of corporate scientific practices and the US regulatory system with respect to GE foods, with special reference to several commercialized crops and relevant (international) standards. We focus on the US regulatory system because the US has far more GE crops on the market than any other nation, and because American regulatory agencies are so often cited in support of the safety of these foods. We then outline an initial screening regimen for GE foods that, if made mandatory, would in our opinion better protect public health than the current US system.

This report was not mentioned in the HC GMO Task force report. Either the Task Force ignored the public presentation (and did not read the handouts) or they intentionally chose to omit a peer-reviewed article that raised questions about GMOs. It is likely that task force members would otherwise have no knowledge of the studies detailed in the paper as Schubert mentions in the introduction:

It should be noted at the outset that this study relies heavily on material largely unknown to the broader scientific community, including several unpublished corporate studies, reports on specific GE crops and their regulation by expert bodies (e.g. committees of the National Academy of Sciences) and documents issued by US regulatory agencies.

As a result of either reviewing the wrong study or refusing to acknowledge the conclusions of Schubert/Freese and other scientists referenced in the paper, the primary claim made in this section by the task force is incorrect:

"It is acknowledged that Schubert has identified the problems that may possibly occur. *However, they are all predictions.*"³⁴ (emphasis added)

³³ Mark Phillips personal communication with Dr. Arpad Pusztai. Mr. Steinmaus, task force member, never produced the personal communication referenced in the report to Mr. Phillips.

³⁴ SLO GMO Task Force, p17.

One of the main points of Dr. Reinstein's talk was a well-documented effect that has occurred in GMO corn. GMO corn genetically engineered to express the Bt pesticide has an increase in lignin³⁵.

This effect, discussed at length in the Freese and Schubert paper, is verified in a follow up refereed journal article, *Journal of Environmental Quality* 34: 1508-1518 (2005), which states:

“Transformation of crops, including maize with the Bt gene to combat lepidopteron pests results in pleiotropic effects regarding lignin biosynthesis.”³⁶

FDA scientists urged the organization to not disregard pleiotropic effects in biotech regulation. Dr. Louis Pribyl made the following comment in a memo responding to the Biotech Policy document in 1992:

When the introduction of genes into plant's genome randomly occurs, as is the case with the current technology (but not traditional breeding), it seems apparent that many pleiotropic effects will occur. Many of these effects might not be seen by the breeder because of the more or less similar growing conditions in the limited trials that are performed.³⁷

This indeed turned out to be the case with the increased lignin content of Bt corn.

Finally, it should be noted that Beachy, cited by the HC GMO Task Force report, has extensive financial ties to GMO producers.³⁸

The credentials of David Schubert follow:

David Schubert, PhD is on the faculty of the Salk Institute of Biological Studies in San Diego, California, where he is head of the Cellular Neurobiology Laboratory. He has a B.A. in chemistry and a Ph.D. in cell biology. Dr. Schubert's fields of scientific expertise are molecular genetics, cell biology, and protein chemistry. He has published over 200 reviewed manuscripts in these areas and has written and lectured on the potential health hazards associated with genetically modified crops.

Showa Denko L-Tryptophan

In the USA in 1989 a total of 5000 individuals became ill after consuming an amino acid L-Tryptophan health food supplement. 37 people died and 1500 became permanently disabled.

³⁵ Lignin is the substance in plants that provides the “woody” structure to hold up the plant.

³⁶ “Molecular Composition of Leaves and Stems of Genetically Modified Bt and Near-Isogenic Non-Bt Maize—Characterization of Lignin Patterns” Juergen Poerschmann^{a,*}, Achim Gathmann^b, Juergen Augustinc, Uwe Langera and Tadeusz Góreckid, <http://tinyurl.com/ft5v5>

³⁷ Refer to Appendix for actual FDA memo

³⁸ Dr. Beachy is the founding president of the Danforth Plant Science Center, which was established with a \$70-million pledge from Monsanto. <http://tinyurl.com/q9el7>

All cases of the eosinophilia-myalgia syndrome (EMS) epidemic were traced to the ingestion of L-Tryptophan from a single manufacturer, Showa Denko. All of Showa Denko's L-Tryptophan was created using genetically engineered bacteria. None of the other manufacturers of L-Tryptophan used a genetically engineered process and there are no reports of their customers suffering any ill effects.

Since all samples of the genetically engineered version of L-Tryptophan were destroyed immediately after the EMS cases were discovered, no conclusive determination can be made regarding the cause. It is still debated whether the presence of the toxin was a direct result of the genetic engineering or a bad filtration process.

Many scientists point to genetic engineering as the cause for two main reasons:

1. Many of the cases of EMS occurred BEFORE the Showa Denko filtration process was changed rules out this conclusion.
2. In response to the EMS epidemic, the FDA banned the sale of L-Tryptophan by all manufacturers. This is not the response one would expect if the problem were inadequate filtration by a single manufacturer.

The national EMS association takes this position on the controversy with the help of Gerald Gleich, M.D., the leading expert on the issue:

"The specific contaminant has never been identified." [emphasis in original]

"Even though the bacteria used to produce L-Tryptophan were genetically modified, there is insufficient evidence to prove that these modifications were solely [emphasis in original] responsible for the contaminants linked to the illness Eosinophilia Myalgia Syndrome."³⁹

The task force ignored these facts and, with no scientific backing, provides the US government and industry response:

"In actuality, the toxic contaminant in the dietary supplements was found to be the result of an elimination of a key purification process and NOT [emphasis in original] from the bacteria being genetically engineered..."

³⁹ <http://www.nemsn.org/cause.htm>

Nutrition Section Overview

This section provides very little insight into how GMOs are actually being tested from a nutritional perspective. Instead, it merely speculates on how testing might be accomplished. For example:

| The extent of testing would likely depend on the extent of genetic difference between the source and recipient species. (p22)

In reality, there is no required testing. Rather the producer of the GMO crop decides what nutritional testing is appropriate. Since the corporate nutritional studies are proprietary, one can easily speculate that the ideal case testing is occurring in the absence of any real evidence. Unfortunately, one can just as easily speculate that poor testing is being done.

The nutrition section also attempts to dismiss testing efforts as too cumbersome:

| Two questions arise. 1) How do you look for an unknown something, which may or may not exist? 2) How do you prove something is 100% safe? Neither question has an obvious practical answer.

However, the companies are already (allegedly) performing nutritional tests. Why are the full tests not available for public scrutiny and peer review?

Finally, this section speculates that stomach lesions found during feeding tests would prevent the release of a GMO crop. However, the FDA was aware that the FlavrSavr tomato caused unexplained stomach lesions in rats but the FlavrSavr was still released.⁴⁰

⁴⁰ See Appendix D: FlavrSavr Tomato Approval Despite Stomach Lesions

National Academy of Sciences Section Overview

This section provides many references to theoretical guidelines on how testing might be improved for GMO crops. However, it fails to mention that no action towards implementation of the NAS recommendations has been made by our regulatory agencies over two years after the publication of the report.

With GMOs there was – and continues to be – no choice. Americans have unknowingly become part of a massive experiment.

The fact that the federal government is failing to reform the regulatory process justifies the SLO County Health Commission taking local actions to protect our citizens from the clearly identified – but not sufficiently mitigated – health hazards associated with GMO crops.

In this section is also an attempt to imply risk as an acceptable part of everyday life because nothing can be proven safe:

So the question will always be one of balance. There is a continuum of people in society from those that do not want any risk to those that climb mountains. This is important because as has pointed out earlier in this report, it is impossible to demonstrate absolute safety; and you can only test for what seems probable.

The failure of logic in this statement is that people freely choose to climb mountains. With GMOs there was – and continues to be – no choice. Americans have unknowingly become part of a massive experiment.

Ultimately, any increased risk undertaken consuming or being exposed to GMO foods or pollen is unacceptable. There was no need to add any risk to our food supply. The US taxpayers heavily subsidize the production of all the primary GMO crops - corn, cotton, and soybeans - because we grow too much of them.

Mentioned earlier in the same section is this statement:

It is important to note that these crops first were grown on a large scale in the middle 1990s and, therefore, foods made [from GMOs] have been in our food supply for nearly ten years now.

This statistic would surprise many Americans who have no idea that genetically engineered foods are already in grocery stores. This fact, however, should not be justification for accepting GMO crops without a demand for more complete and transparent testing.

Appendix A: Dr. Linda Kahl, FDA Memo (Page 1)

More documents available online at: <http://www.biointegrity.org/list.html>

Jim -

Here are my comments on the Federal Register document
"Statement of Policy: Foods from Genetically Modified Plants".

1. What is the objective of this policy statement? I see the following possibilities, based on what is in the document:
 - a. To respond to numerous requests to the agency to clarify our position with respect to the use of the new techniques of biotechnology, and specifically genetic engineering, to produce new cultivars of food crops.
 - b. To prepare a comprehensive agency policy with respect to new cultivars of food crops - regardless of whether those food crops are prepared by new or traditional methods.

The current document (particularly the section on scientific issues and the appendix) is very schizophrenic in regard to the objective. Some of this has been provoked by conflicting comments from multiple sources on previous drafts. Some advice has been "the recommended actions should be the same for cultivars developed by new and traditional methods, because it is the product and not the process that is regulated". Other advice has been "Do you realize that you are proposing regulations for an entire industry that has previously been virtually unregulated and has a history of safety" (i.e., traditional plant breeding).

Therefore, perhaps the relevant question is not only what the objective of the document as a whole is, but what the objective of the Appendix is. Should this in fact be "Points to Consider" for new methods of biotechnology, since guidance has been requested, and guidance on traditional breeding has already been given (GRAS symposium, CFR)? Can the objective of the Appendix be "A" even if the objective of the policy statement is "B"?

The June 1986 Coordinated Framework does not seem to be so concerned with traditional methods and makes no apologies for discussing only biotechnology. It is very concerned with making it clear that no new legislation is needed. It notes that the framework seeks to distinguish those organisms that need review and those that do not. So why can't the current appendix deal only with new biotechnology? Why try to make it appear that we are discussing all modified crops?

2. I believe that there are at least two situations relative to this document in which it is trying to fit a square peg into a round hole. The first square peg in a round hole is that the document is trying to force an ultimate conclusion that

The HC
GMO Task
Force
suffers
from similar
problems
as it
attempts to
lump
traditional
methods
and GMOs
into similar
risk
categories.

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Dr. Linda Kahl, FDA Memo (Page 2)

It was a political mandate to NOT regulate the genetic engineering process. The decision was not based in science then and it still isn't today.

there is no difference between foods ~~produced~~ ^{created} by genetic engineering and foods modified by traditional breeding practices. This is because of the mandate to regulate the product, not the process.

The FDA's own scientific experts felt that transgenic crops led to different risks. They were ignored when developing policy.

- a. The processes of genetic engineering and traditional breeding are different, and according to the technical experts in the agency, they lead to different risks. There is no data that addresses the relative magnitude of the risks - for all we know, the risks may be lower for genetically engineered foods than for foods produced by traditional breeding. But the acknowledgement that the risks are different is lost in the attempt to hold to the doctrine that the product and not the process is regulated.
- b. I don't see how the acknowledgement of the fact that the risks are different compromises the position that it is the product that is regulated. The "Points to Consider" ~~for products of genetic engineering must be different than the "Points to Consider" for products of traditional breeding - how can you expect a traditional breeder to have the most basic molecular data (e.g. DNA sequence of the inserted material) when he has no idea of the molecular identity of the genetic material being introduced? Are we to insinuate that practitioners of genetic engineering do not need to adhere to the most basic level of good laboratory techniques simply because the traditional breeding community cannot also provide that data?~~

- 3. The second square peg in a round hole is that the approach of at least part of the document is to use a scientific analysis of the issues involved to develop the policy statement.
 - a. In the first place, are we asking the scientific experts to generate the basis for this policy statement in the absence of any data? It's no wonder that there are so many different opinions - it is an exercise in hypotheses forced on individuals whose jobs and training ordinarily deal with facts.
 - b. In the second place, I don't think that the scientific analysis as presented is complete. The scientific issues section of the document talks of the "possibility of unintended, accidental changes in genetically engineered plants" but I believe that in most cases the word "risk" is avoided. This is probably at least partly due to the fact that there is no data that could quantify risk. But if the scientific issues section of the document deals totally in hypotheses about "possibilities", why does it not address the fact that multiple events would have to

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Dr. Linda Kahl, FDA Memo (Page 3)

occur in order for the "possibility of unintended, accidental changes in genetically engineered plants" to result in a danger to the public health. Surely the following series of events must all occur in order to present a danger to the public health: (1) The accidental change must activate a pathway for production of a toxin that was unanticipated, or for which there is no suitable analytical method. (2) This unanticipated toxin must be expressed at a high enough level to exert an effect. (3) This toxin must have serious adverse consequences to humans and/or animals that consume it. (4) The presence of this dangerous unanticipated toxin in amounts sufficient to cause a public health problem must not manifest itself in any other way, so that the first and only clue will be the "body count", so to speak.

I wonder if part of the problems associated with this approach - using scientific issues to set the stage for the policy statement - are due to the fact that the scope of technical experts assigned to the project did not include any whose usual job is risk analysis. This does not eliminate the problem with a lack of data, but if the molecular biology, chemistry, and toxicology experts are being forced to deal with hypotheses rather than data, why not the risk analysis experts?

Are there any alternatives to toxicology testing that could tip the scales to a level where the modified food can meet a safety standard of reasonable of no harm? My impression is that the limitation of the number of insertion sites to one is not sufficient - what does that actually tell you about safety? Could a recommendation that any new cultivars that are produced by genetic engineering only be used (at least for the present) after they have been crossed by traditional breeding into an established cultivar take us over the edge to where no tox testing is necessary? Is that what we expect the plant breeding community to be doing anyway? If so, then such a suggestion is not a burden.

5. If we don't get specific and substantial input from CVM on animal feed, should the objective be reduced to human food?
6. This is a minor comment in relation to the overall problems in the document, but there needs to be a decision as to whether we use one phrase exclusively to refer to certain issues/topics/procedures (i.e. to promote clarity), or if we use multiple terms to liven the document up. E.g. the document tends to use the phrase "new methods of biotechnology" in its entirety when applicable; but the document uses "traditional breeding practices", "conventional plant breeding", "classical plant breeding",

What if a problem takes years to manifest itself? What if it increases asthma or Type 2 diabetes or causes acid reflux disease - all of which have spiked since the introduction of GMOs.

Appendix B: Dr. Louis Pribyl Lack of Science, FDA memo

More documents available online at: <http://www.biointegrity.org/list.html>

This is still a common tactic of GMO supporters and used in the HC GMO task force report.

DRAFT

LOUIS J. PRIBYL
3/6/92
Comments on Biotechnology Draft Document, 2/27/92

-What has happened to the scientific elements of this document? Without a sound scientific base to rest on, this becomes a broad, general, "What do I have to do to avoid trouble"-type document. The examples do not supply the scientific rationale that is needed. A scientific document is needed, because there is very little (even when things are called scientific) scientific information supplied. If the FDA wants to have a document based upon scientific principles these principles must be included, otherwise it will look like and probably be just a political document.

-This document reads like a biotech REDBOOK!! The initial intent of the document was to present scientific considerations and to avoid telling industry what tests to run and how to go about doing it, but the flow charts do just what (initially) was to be avoided.

-It reads very pro-industry, especially in the area of unintended effects, but contains very little input from consumers and only a few answers for their concerns, many of which would be answered by supplying the scientific grounding principles.

-The document is inconsistent, in that it says (implies) that there are no differences between traditional breeding and recombinant, yet consultations, and premarket approvals are being bantered around, when they have not been used for foods before. In fact the FDA is making a distinction, so why pretend otherwise.

-The unintended effects cannot be written off so easily by just implying that they too occur in traditional breeding. There is a profound difference between the types of unexpected effects from traditional breeding and genetic engineering which is just glanced over in this document. This is not to say that they are more dangerous, just quite different, and this difference should be and is not addressed.

-A lot of time is spent on selectable markers, which in reality will not be of much concern with the advent of several ways to disarm the marker gene. If the length of the section is any indication of the level of concern, then this is way out of proportion.

-The flow charts are just a version of the Redbook, hoops through which industry must jump, and not scientific considerations. Industry will do what it HAS to do to satisfy the FDA "requirements" and not do the tests that they would normally do because they are not on the FDA's list.

-Why should companies conduct tests as described in the flow charts if there are no differences between traditional foods and those produced by modern technology? And what are the regulatory grounds for all the "shoulds" that are spread throughout this document? If industry does not follow these "should" items is the FDA going to perform these tests and penalize the companies or does the Agency wait for something to go wrong and then act?

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Specific Comments
-pg.3, line 24 (and elsewhere)- How many "first" examples will

Appendix C: Dr. Louis Pribyl, Pleiotropic Effects, FDA memo

More documents available online at: <http://www.biointegrity.org/list.html>

Pleiotropic effects should not be dismissed.

3

products, rather than more. This will mean less concern about safety, because of a false sense of "knowing what one is doing" and "its been done hundreds of times before without a problem, why check it now".

-pg.15-16, Unexpected Effects- This is industry's pet idea, namely that there are no unintended effects that will raise the FDA's level of concern. But time and time again, there is no data to backup their contention, while the scientific literature does contain many examples of naturally occurring pleiotropic effects. When the introduction of genes into plant's genome randomly occurs, as is the case with the current technology (but not traditional breeding), it seems apparent that many pleiotropic effects will occur. Many of these effects might not be seen by the breeder because of the more or less similar growing conditions in the limited trials that are performed. Until more of these experimental plants have a wider environmental distribution, it would be premature for the FDA to summarily dismiss pleiotropy as is done here.

-pg.38, line 8- "FDA has also been asked whether foods developed by with... (delete the word with).

-pg.42, lines 1-4- The potential for activating cryptic pathways has **NOT** "been effectively managed in the past by sound agricultural practices", because the breeders have not had to face the issue of new, powerful regulatory elements being randomly inserted into the genome. So there is no certainty that they will be able to pick up effects that might not be obvious, such as cryptic pathway activation. This situation IS different than that experienced by traditional breeding techniques.

-pg.45, Chart II, box that reads- "Is the host plant or related species a source of toxicants?" All plants produce toxicants, so the answer to this question is always YES. Many of these toxicants are directed against insects or other herbivores, and so there is little knowledge as to their effect on humans. At their native dose ranges, they might be benign, but if they are increased by unintended effects, their effect(s) are unknown. So to just say "No problem" would be premature and potentially unsafe.

-pg.46, Chart III, box that reads- "Is there clear evidence that allergens have not been transferred to host?" Since there are very few allergens that have been identified at the protein or gene level, this question can only be answered "No" when the gene comes from a plant which produces allergies. So the companies are going to have to consult FDA on tomatoes, peanuts, wheat, and every other plant which produces allergic reactions. Also the only definitive test for allergies is human consumption by affected peoples, which can have ethical considerations.

-pg.46, Chart III, box that reads- Donor a source of toxic substances? SEE ANSWER TO pg.45, Chart II.

-pg.46, Chart III, box that reads- "Evidence that the donor toxic..." Donor should read DONOR'S.

-pg.47, Chart IV, box that reads- "Newly introduced protein present in food from the plant?" This does not take into account, nor does the document as a whole, those introduced proteins

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Appendix D: Sample Freedom of Information Act Request

Fill out request online at: <https://foia.aphis.usda.gov/request.html>

Attention: USDA 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 and field test site applications for genetically engineered crops conducted in San Luis Obispo County, California and including Cal Poly University during the years 2004 through July 2006.

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,

Appendix E: FlavrSavr Tomato Approval

Page 9 - FLAVR SAVR™ Tomatoes

CFSAN scientists commented on the information provided by Calgene, and the conclusions reached by Calgene, concerning levels of tomatine and other glycoalkaloids in FLAVR SAVR™ tomatoes, as follows: The information supplied by Calgene supports Calgene's observation that the tomatine levels in vine-ripened FLAVR SAVR™ tomatoes are comparable to the tomatine levels in commercial tomato varieties. Calgene's data also provide evidence that neither FLAVR SAVR™ tomatoes nor commercial control tomato varieties contain other glycoalkaloids at levels measurable with the HPLC method used.

New Proteins Introduced into FLAVR SAVR™ Tomatoes

As noted above, in developing FLAVR SAVR™ tomatoes, Calgene used APH(3')II as a selectable marker to identify plant cells carrying the antisense PG gene. Calgene provided data and information addressing the safety of APH(3')II, including the direct effects of ingestion (i.e., the effect of antibiotics). FDA petition (FAP 3A-aid in the development of, a plants, tomatoes.

Link to full FDA memo available online:
<http://www.cfsan.fda.gov/~acrobat2/bnfMFLV.pdf>

Animal Gavage Studies

Introduction

When Calgene approached FDA in 1991, while the agency was developing the 1992 policy statement, the firm indicated that they wished to provide additional assurance that all possible tests to establish the safety of this first example of a food derived from a new plant variety developed using recombinant DNA techniques had been performed. One question raised was whether toxicological studies could help to determine whether unexpected toxicants might be present in FLAVR SAVR™ tomatoes. Although there are no well established toxicological approaches to testing the safety of whole foods, Calgene accepted an agency suggestion (Refs. 7 and 8) that the firm conduct a short-term feeding study in rodents. The firm then designed and conducted three rat gavage studies.

Results

Calgene submitted data from three short-term (28-day) gavage studies, conducted at the International Research and Development Corporation (IRDC), in which groups of male and female rats were given (by gavage) deionized water, control (nontransgenic) tomatoes, or FLAVR SAVR™ tomatoes. IRDC identified no biologically significant changes in body weight, organ weight, food consumption, hematologic parameters or clinical chemistry findings in any of the three studies. In addition, in the first study, IRDC identified no adverse findings that could be related to consumption of FLAVR SAVR™ tomatoes following complete gross and microscopic examination of a comprehensive selection of tissues. In the second and third studies, however, IRDC

The following page contains details on the two of three studies that caused stomach lesions.

FlavrSavr Tomato Approval Despite Stomach Lesions (continued)

Page 10 - FLAVR SAVR™ Tomatoes

noted gastric erosions in some animals. These findings on the gastric erosions are discussed below.

Gastric Erosions

In the first study, groups of male and female rats were given by gavage either (1) deionized water; (2) homogenized FLAVR SAVR™ tomatoes obtained from a noncommercial tomato line; or (3) homogenized nontransgenic tomatoes. IRDC reported no gastric erosions in rats from any group. (See Table 1.)

In the second study, groups of male and female rats were given by gavage either (1) deionized water; (2) homogenized nontransgenic CR3 tomatoes; (3) homogenized FLAVR SAVR™ tomatoes obtained from the CR3-613 tomato line; or (4) homogenized FLAVR SAVR™ tomatoes obtained from the CR3-623 tomato line. In this second study, IRDC reported gastric erosions in four of twenty female rats given CR3-623 FLAVR SAVR™ tomatoes, but not in rats in any other group. (See Table 1.)

In the third study (which was designed in an attempt to clarify the results of the second study), groups of male and female rats were given by gavage either (1) deionized water; (2) homogenized nontransgenic CR3 tomatoes; (3) lyophilized nontransgenic CR3 tomatoes;³ (4) homogenized CR3-623 FLAVR SAVR™ tomatoes; (5) lyophilized CR3-623 FLAVR SAVR™ tomatoes grown in one geographical location; or (6) lyophilized CR3-623 FLAVR SAVR™ tomatoes grown in a second geographical location (females only). In this third study, IRDC reported gastric erosions in eight of eleven groups. (See Table 1.)

At the request of Calgene, PATHCO, Inc., assembled a panel of pathologists (the Pathology Working Group or PWG), who conducted a review of coded microscopic slides containing stomach sections from all three studies to evaluate the incidence and significance of the observed gastric erosions. (See Table 1.) Also at the request of Calgene, ENVIRON Corporation prepared a summary of Calgene's overall safety assessment of FLAVR SAVR™ tomatoes and assembled an expert panel to review that summary. The PWG concluded, and the expert panel concurred, that the gastric erosions observed were incidental and not test article related. Calgene submitted to CFSAN the original data from the IRDC studies, the PWG report on the three gavage studies, and the conclusions of the expert panel.

³ The amount of homogenized tomatoes administered to the rats in each study was equivalent to a human consumption of approximately 10 large or 40 small (e.g., plum) tomatoes per day. The use of tomatoes that were lyophilized and reconstituted to 50% of the original volume doubled the dose of tomatoes (i.e., approximately 20 large or 80 small tomatoes) compared to the dose that could be achieved using homogenized tomatoes.

This is now a common tactic in animal feeding studies. When negative results occur for just the GMO, a new test is designed.

Gastric erosions in transgenic tomatoes are dismissed as incidental even though no explanation can be provided.

Appendix F: Pusztai Research Responses

Response to blank vector argument in Lancet Vol 354, page 1726-1727, 13-Nov-1999:

“Lachmann [president of the UK’s Academy of Medical Sciences] says that the experiments need to be repeated. We would be happy to oblige. If our experiments are so poor why have they not been repeated in the past 16 months? It was not we who stopped the work on testing GM potatoes expressing GNA or other lectins or even potatoes transformed with the empty vector, which are now available. If Lachmann represents the view of the Academy of Medical Sciences on GM-food safety he should use his influence to make funds available for the continuation of this work in the UK.”

Dr. Pusztai’s response to the “archaic formalin fixation ... methods” published in the Lancet:

“There might not be an ideal fixative but it is mischievous to suggest that the fixative upon which the whole of human histopathology relies could be responsible for different crypt-length measurements.”

Lancet editors (Vol. 353, page 1811, 29-May-1999) response to comments made by the British Royal Society that “no meaningful conclusion could be reached from Ewen and Pusztai’s experiments”:

“Last week (May 22, p1769) we reported that the Royal Society had reviewed what it could of Pusztai and colleagues’ evidence and found it flawed, a gesture of breathtaking impertinence to the Rowett Institute scientists who should be judged only on the full and final publication of their work.”

Dr. Pusztai had these comments on the same subject:

On this same topic, Arpad writes in the Lancet (Volume 354, Number 9179, 21 August 1999):

“Your editorial correctly notes that not all the facts were in the possession of the Royal Society. Thus, it is difficult to understand how they could deduce that the GM-potato experiments were ‘badly designed and poorly carried out’ from an internal report by Pusztai that contained no such details. The Royal Society had never considered, or even asked for, a copy of the original research proposal of 1995. This omission was further compounded by the Royal Society’s unwillingness to take up Pusztai’s offer of full cooperation. Moreover, as crucial details of the histological findings were never divulged to them, it is more than perplexing that the Royal Society’s unnamed experts were so emphatic in their condemnation of the GM-potato experiments.”

Appendix F: Pusztai Research Responses (continued)

The 23 scientists from 13 nations who reviewed Dr. Pusztai's research had this to say:

"Those of us who have known Dr. Pusztai's work or have collaborated with him were shocked by the harshness of his treatment by the Rowett and even more by the impenetrable secrecy surrounding these events.

It is an unacceptable code of practice by the Rowett and its Director, Professor James, to set themselves up as arbiters or judges of the validity of data which could have such a profound importance not only for scientists, but also for the public and it's health."

Appendix F: Pusttai Research Responses (continued)

The independent scientists who reviewed Dr. Pusttai's data and case are:

Prof. K. Baintner, Department of Physiology, Pannon Agricultural University, Kaposvar, Hungary

Profs. B.S. Cavada, R. de Azevedo Moreira, A.F.F.U. de Carvalho, M. de Guia Silva Lima, J.T.A. de Oliveira, I.M. Vasconcelos (previous PhD students and/or collaborators of Dr. Pusttai) Universidade Federal do Ceara, Fortaleza, Brazil

Prof. J. Cummins, Emeritus Prof. Genetics, Ontario, Canada Dr. S.W.B. Ewen, Department of Pathology, Aberdeen Royal Hospitals, Aberdeen, Scotland, UK

Prof. R. Finn, Department of Medicine, The University of Liverpool, United Kingdom Prof. M. Fuller, Stony Brook, NY 11790, USA

Prof. B.C. Goodwin, Schumacher College, Dartington, Devon, United Kingdom

Dr. J. Hoplichler, Federal Institute for Less-Favoured and Mountainous Areas, Vienna, Austria

Dr. C.V. Howard, Fetal and Infant Toxicology, The University of Liverpool, United Kingdom

Dr. J. Koninkx, Department of Pathology, Faculty of Veterinary Medicine, University of Utrecht, The Netherlands

Prof. A. Krogdahl, Norwegian School of Veterinary Science, Oslo, Norway Dr. K. Lough, Bankhead, Aberdeen, Scotland (formerly of the Rowett Research Institute, Aberdeen, Scotland, UK) PD.

Dr. D. Mayer, Heidelberg, Germany

Prof. F.V. Nekrep, Biotechnical Faculty, Zootechnical Department, University of Ljubljana, Slovenija

Prof. S. Pierzynowski, Department of Animal Physiology, University of Lund, Sweden

Prof. S. Pongor, Protein Structure and Function Group, International Centre for Genetic Engineering and Biotechnology, Trieste, Italy

Prof. I. Pryme, Department of Biochemistry and Molecular Biology, University of Bergen, Norway

Prof. J. Rhodes, Gastroenterology Research Group, The University of Liverpool, United Kingdom

Dr. L. Rubio, Department of Animal Nutrition, Estacion Experimental del Zaidin, Granada, Spain

Prof. M. Sajgo, Department of Chemistry and Biochemistry, Godollo University of Agriculture, Hungary

Prof. U. Schumacher, Department of Neuroanatomy, University of Hamburg, Germany

Dr. B. Tappeser, Institute for Applied Ecology, Freiburg, Germany

Prof. T. Wadström, Department of Medical Microbiology, University of Lund, Sweden

Appendix G: USDA, Inc. Executive Summary Excerpt

IN ITS EARLY DAYS, the United States Department of Agriculture (USDA) was dubbed the “People’s Department” by President Lincoln, in recognition of its role in helping the large portion of the population that worked the land. Some 140 years later, USDA has been transformed into something very different. Today it is, in effect, the “Agribusiness Industry’s Department,” since its policies on issues such as food safety and fair market competition have been shaped to serve the interests of the giant corporations that now dominate food production, processing and distribution. We call it USDA Inc.

[...]

The extent to which agribusiness has packed USDA with its people is apparent when looking at the biographies of the top officials of the Department, up to and including Secretary Ann Veneman. In addition to her time as a public official, Veneman served on the board of biotech company Calgene ([producer of the FlavrSavr tomato] and later taken over by Monsanto). Many of Veneman’s key aides and the heads of various USDA agencies are political appointees who spent much of their career working for agribusiness companies and trade associations.

[...]

BIOTECH FOODS. Resistance to genetically modified (GM) wheat among farmers has become so strong that Monsanto Co. announced recently that it was abandoning active efforts to develop GM wheat. USDA, nonetheless, remains one of the strongest proponents of agricultural biotechnology. Like her predecessor Dan Glickman, Secretary Veneman has promoted GM foods in international forums, downplaying the safety issues and charging that biotech critics are impeding efforts to reduce world hunger.

As noted previously, Veneman once served on the board of a biotech company. Neil Hoffman, the Biotechnology Regulatory Services Director of USDA’s Animal and Plant Health Inspection Service, formerly worked for the biotech firm Paradigm Genetics. Nancy Bryson, USDA’s general counsel, was formerly a partner in the law firm of Crowell & Moring, where she co-chaired the firm’s corporate biotechnology practice.

The full USDA, Inc. report is available online at:

<http://www.agribusinessaccountability.org/>

Appendix H: Summary of UCS FDA Survey

The Union of Concerned Scientists (UCS) and Public Employees for Environmental Responsibility (PEER) distributed a 38-question survey to nearly 6,000 scientists at the U.S. Food and Drug Administration (FDA) to obtain their perceptions about scientific integrity in the agency. Nearly 1,000 scientists filled out and returned the survey. Unless otherwise specified, the points below refer to the percentage of scientists at the entire agency who responded to the survey.

I. Interference with Scientific Determinations at the FDA

Large numbers of agency scientists reported interference with their scientific work:

- Almost one in five (18 percent) responded, "I have been asked, for non-scientific reasons, to inappropriately exclude or alter technical information or my conclusions in an FDA scientific document."
- More than three in five (61 percent) knew of cases in which "Department of Health and Human Services or FDA political appointees have inappropriately injected themselves into FDA determinations or actions."
- Three in five (60 percent) also knew of cases "where commercial interests have inappropriately induced or attempted to induce the reversal, withdrawal or modification of FDA determinations or actions." Fifty percent also felt that non-governmental interests (such as advocacy groups) had induced or attempted to induce such changes.

II. Negative Effect on Public Health

FDA scientists' responses suggest that the agency's ability to fulfill its mission—protecting public health—is being put at risk:

- Only half (51 percent) feel the "FDA is acting effectively to protect public health."
- Less than half (47 percent) think that the "FDA routinely provides complete and accurate information to the public."
- Less than half (49 percent) agree that "FDA leadership is as committed to product safety as it is to bringing products to the market."

III. Chilling Effect on Scientific Candor

Agency scientists report being afraid to speak frankly about safety concerns and feel constrained in their roles as scientists:

- One-fifth (20 percent) say they "have been asked explicitly by FDA decision makers to provide incomplete, inaccurate or misleading information to the public, regulated industry, media, or elected/senior government officials." In addition, more than a quarter (26 percent) feel that FDA decision makers implicitly expect them to "provide incomplete, inaccurate, or misleading information."
- Two in five (40 percent) said they could not publicly express "concerns about public health without fear of retaliation." More than a third (36 percent) did not feel they could do so even inside the confines of the agency.

IV. FDA Scientists Face Immense Pressures

FDA scientists reported that they have inadequate resources to perform even the basic work of the agency. The lack of resources and other pressures have strained scientists' morale:

- Nearly 70 percent do not believe the FDA has sufficient resources to effectively perform its mission of "protecting public health . . . and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health."
- Less than half (44 percent) say they "respect the integrity and professionalism of FDA leadership."
- Two in five (40 percent) describe their morale as poor to extremely poor, while a mere four percent rate their morale as excellent.
- More than half (52 percent) say their personal job satisfaction has decreased over the past few years, while only 18 percent say their job satisfaction has increased.
- Less than a third (32 percent) think the agency "is moving in the right direction."

V. Scientists Recommend Changes at the Agency

FDA scientists had strong opinions about reforms that would address some of their concerns:

- Nearly two in three (63 percent) said that the "laws and regulations that govern FDA, including the agency's structure, need change for the agency to better serve the public."
- More than four in five (81 percent) agreed that the "public would be better served if the independence and authority of FDA post-market safety systems were strengthened."

Unless otherwise specified, the above percentages refer to the FDA scientists who responded to the survey.

Appendix I: The Mendocino County Precautionary Principle

The Precautionary Principle requires a thorough exploration and a careful analysis of a wide range of alternatives. Based on the best available science, the Precautionary Principle requires the selection of the alternative that presents the least potential threat to human health and the County's natural systems. Public participation and an open and transparent decision making process are critical to finding and selecting alternatives.

Where threats of serious or irreversible damage to people or nature exist, lack of full scientific certainty about cause and effect shall not be viewed as sufficient reason for the County to postpone cost effective measures to prevent the degradation of the environment or protect the health of its residents. Any gaps in scientific data uncovered by the examination of alternatives will provide a guidepost for future research, but will not prevent protective action from being taken by the County. As new scientific data become available, the County will review its decisions and make adjustments when warranted.

Where there are reasonable grounds for concern, the precautionary approach to decision making is meant to help reduce harm by triggering a process to select the least potential threat. The essential elements of the Precautionary Principle approach to decision-making include:

- 1. Anticipatory Action:** There is a duty to take anticipatory action to prevent harm. Government, business, and community groups, as well as the general public, share this responsibility.
- 2. Right to Know:** The community has a right to know complete and accurate information on potential human health and environmental impacts associated with the selection of products, services, operations or plans. The burden to supply this information lies with the proponent, not with the general public.
- 3. Alternatives Assessment:** An obligation exists to examine a full range of alternatives and select the alternative with the least potential impact on human health and the environment, including the alternative of doing nothing.
- 4. Full Cost Accounting:** When evaluating potential alternatives, there is a duty to consider all the reasonably foreseeable short and long-term costs and benefits to public as well as private sectors of the community, even if such costs are not reflected in the price. Some of these costs and benefits may include raw materials, manufacturing, transportation, use, cleanup, eventual disposal, labor, energy, health, safety, and job-creation.
- 5. Participatory Decision-Making Process:** Decisions applying the Precautionary Principle must be transparent, participatory, and informed by the best available information. The County will make a reasonable effort to include the public in an appropriate manner when making decisions that may affect the environment, health, and quality of life.

Executive Summary

Animal and Plant Health Inspection Service Controls Over Issuance of Genetically Engineered Organism Release Permits (Audit Report 50601-8-Te)

Results in Brief

The number of approved applications to field test genetically engineered (GE) crops in the United States has increased significantly since 1986, when the Department began regulating experimental GE plants. Since that time, the U.S. Department of Agriculture (USDA) has approved over 10,600 applications for more than 49,300 field sites. Biotechnology companies are investing millions of dollars to develop new GE plants, some with the goal of commercializing them for use as food, feed, industrial compounds, and medicines. The rapid growth of agricultural biotechnology, and its prominent position in the public eye, increases USDA's responsibility to ensure that regulated GE plants, including their pollen and seeds, do not persist in the environment. However, as the number of approved applications to field test new GE plants continues to rise, we are concerned that the Department's efforts to regulate those crops have not kept pace.

To evaluate the Animal and Plant Health Inspection Service's (APHIS) controls over releases and movements of regulated GE plants, we visited 91 field test sites in 22 States that were either planted or harvested. We inspected the sites for compliance with APHIS' requirements for the growing or postharvest season. We found that APHIS, the USDA agency that oversees biotechnology regulatory functions for the Department, needs to strengthen its accountability for field tests of GE crops. In fact, at various stages of the field test process—from approval of applications to inspection of fields—weaknesses in APHIS regulations and internal management controls increase the risk that regulated genetically engineered organisms (GEO) will inadvertently persist in the environment before they are deemed safe to grow without regulation.

Accountability for GE Crops Needs Improvement

Depending on the nature of the GE crop, APHIS authorizes field tests through two methods: permits and notifications. For field tests of high-risk GE crops, such as those designed to produce pharmaceutical and industrial compounds, APHIS issues permits. For GE crops that APHIS considers low-risk based on its scientific experience with the plants, applicants can use the more streamlined notification process. We found, however, that APHIS lacks basic information about the field test 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.

- Of primary concern, the precise locations of all GE field test sites planted in the United States are not always known. After authorizing field tests,

APHIS does not follow up with all permit and notification holders to find out exactly where the fields have been planted or if they have been planted at all. In some cases, APHIS may only be aware of the State and county where an applicant plans to conduct a field test. Without knowing the locations of all planted field test sites, including their global positioning system (GPS) coordinates, APHIS cannot effectively monitor permit and notification holders' compliance with field test requirements. In January 2005, APHIS issued a memorandum that requested notification holders to voluntarily submit GPS coordinates or other information to identify the field test after planting.

- Before approving field tests, APHIS does not review notification applicants' containment protocols, which describe how the applicant plans to contain the GE crop within the field test site and prevent it from persisting in the environment. Instead, APHIS allows notification holders to provide the protocols verbally if their field test sites are selected for inspection. Since notifications comprise the vast majority of field test authorizations, this policy undermines both the field test approval and inspection processes.
- At the conclusion of the field test, APHIS does not require permit holders to report on 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. As a result, we found that two large harvests of GE pharmaceutical crops remained in storage at the field test sites for over a year without APHIS' knowledge or approval of the storage facility.

In addition, APHIS does not thoroughly document its reviews of applications in the official files. Specifically, APHIS biotechnologists do not sufficiently document their review process and scientific basis for approving initial field test applications. APHIS also does not effectively track information required during the field tests, including approved applicants' progress reports, which should contain the results of field tests, including any harmful effects on the environment. Although we noted that many permit and notification holders submit these required progress reports late or not at all, APHIS does not always follow up to obtain the information.

Weaknesses in Inspections and Enforcement

APHIS' field test inspection process can be improved in a number of areas. Inspection requirements are vague and there is a lack of coordination between the two APHIS units responsible for the inspection program, Biotechnology Regulatory Services (BRS) and Plant Protection and Quarantine (PPQ). BRS is responsible for overall management of the program, while PPQ officers perform most of the actual inspections of GE field test sites. We found that BRS does not have a formal, risk-based process for selecting individual sites

for inspection, and that PPQ does not complete all of the inspections BRS requests, including inspections of pharmaceutical and industrial crops.

For example, we found that PPQ did not inspect all pharmaceutical and industrial field test sites five times during the 2003 growing season, as APHIS has announced to the public. APHIS has also stated publicly that pharmaceutical and industrial field test sites would be inspected twice during the postharvest period, or the year following the end of the field test, during which the field must be monitored for regrowth of the GE crop. In one case, a violation at a pharmaceutical field test site in our sample went undetected because PPQ did not perform the required inspections at that site during the 2003 postharvest monitoring period.

Further contributing to the inspection problem, neither BRS nor PPQ kept track of the total number of inspections that are actually completed. Although APHIS agreed to improve its tracking of inspection reports following an Office of Inspector General (OIG) audit more than 10 years ago, the agency continued to lack an effective, comprehensive management information system to account for all inspections and their outcomes. In fact, we found 11 violations that were not recorded in BRS' compliance infractions database at the time of our audit, even though they were reported to BRS or could have been identified from information BRS already had. APHIS took administrative action on only 1 of those 11 violations.

APHIS subsequently advised us that in September 2004, it had implemented some changes in the inspection process that included an agreement between BRS and PPQ that clarified responsibility for conducting inspections. BRS also developed a methodology for selecting notifications for inspection based upon risk. However, our review of the agreement between BRS and PPQ found that it did not include inspections of nonpharmaceutical and nonindustrial permits. BRS continues to select entire permits and notifications for PPQ to inspect which may cover numerous field test sites. Consequently, BRS has no assurance that the highest risk field sites are inspected. Also, BRS initiated an interim inspection tracking system in February 2005, during our audit, but the effectiveness of this system has not been reviewed or tested by the OIG.

Even if APHIS improves its inspection process, we found that APHIS has not updated its regulations to reflect the Plant Protection Act of 2000, under which APHIS carries out its biotechnology oversight duties. Also, an Office of the General Counsel official advised us that APHIS currently does not have legislative authority to hold applicants financially responsible for costs incurred by USDA due to an unauthorized release of regulated GEOs. Because APHIS cannot require applicants to provide proof of financial responsibility before it authorizes field tests, USDA may have to bear the expense of removing GE material from the environment in the event of an unintentional release.

Inadequate Guidance for Containing GE Crops and Seeds

Finally, we found that APHIS guidance should be strengthened to prevent the persistence of GE crops outside the field test. For example, APHIS does not specify when GE crops must be destroyed, or “devitalized,” following the field test. Approved applicants sometimes allow harvested crops to lie in the field test site for months at a time, their seeds exposed to animals and the elements. Also, because APHIS has not specifically addressed the need to physically restrict edible GE crops from public access, we found a regulated edible GE crop, which had not gone through the Food and Drug Administration’s regulatory process for approval for human consumption, growing where they could easily be taken and eaten by passersby.

GE crops have come to play an important role in American agriculture, and many crops currently being field tested will eventually be approved as safe to grow and eat without regulation. However, while they remain under USDA’s jurisdiction, GE crops and harvests—especially those developed for pharmaceutical and industrial purposes—must be carefully regulated. Although we noted relatively few violations of existing requirements at the time of our field visits, we concluded that APHIS’ current regulations, policies, and procedures do not go far enough to ensure the safe introduction of agricultural biotechnology. To meet its strategic goals and inspire public confidence in USDA’s biotechnology regulatory program, APHIS must continue to refine and strengthen the GEO field release process.

Recommendations In Brief

To maintain accountability for regulated GE crops, APHIS needs to require more information both prior to and during the field test. Specifically, APHIS needs to:

- obtain GPS coordinates of all planted field test sites, enabling APHIS to identify where regulated GE crops are planted at any given time;
- obtain all applicants’ scientific protocols for conducting field tests;
- obtain reports on the final disposition of high-risk pharmaceutical and industrial harvests; and
- seek legislative authority to require permit applicants, based on the level of risk, to provide proof of financial responsibility, in the event of an unauthorized GEO release.

To strengthen monitoring of GE field test sites, APHIS needs to formalize its inspection process and assign and coordinate the responsibilities of BRS and PPQ. APHIS also needs to update its regulations and develop a comprehensive management information system for tracking the receipt and review of all information associated with GEO release permits and notifications.

Finally, to make sure that approved applicants take appropriate steps to prevent GE crops from proliferating outside the field test site, APHIS needs to develop guidance that specifically addresses devitalization deadlines and edible crops.

Agency Response

In its response dated November 2, 2005, APHIS officials generally agreed with OIG's recommendations and have completed or began implementing 23 of the 28 recommendations in the report.

APHIS is in the process of requiring GPS coordinates of each field site on the 28-day planting reports, requiring the reporting of the disposal of GE pharmaceutical and industrial harvest in the field report submitted 21 days prior to harvest, and obtaining a determination from the Office of the Secretary to seek legislative authority to require applicants to provide proof of financial responsibility in the event of an unauthorized GEO release.

APHIS has established a Memorandum of Understanding (MOU) between BRS and PPQ to formalize inspection responsibilities, better coordinate inspections in regions, and ensure inspections are completed in a timely manner. APHIS is in the process of updating, consolidating and clarifying its regulations in regards to GE regulated field releases and incorporating provisions of the Plant Protection Act of 2000. APHIS has also designed a single management information system for tracking permit and notification inspections and field test reports.

APHIS disagreed with recommendations associated with obtaining notification applicants' scientific protocols for conducting field tests, reviewing these protocols by biotechnologists, and distributing these protocols to PPQ officers to use in conducting inspections of field sites under notification. APHIS also contends that the current system of performance-based regulatory standards for notifications is effective at protecting the American agriculture. Lastly, APHIS did not agree with developing policy guidelines for restricting public access to edible regulated crops when conducting field tests and with developing policies and procedures for selecting specific field test sites for inspection based on risk.

OIG Position

We generally concur with APHIS' response for 23 of the 28 recommendations in the report and have reached management decision on one recommendation. Actions necessary to reach management decision on the remaining recommendations are discussed in the Findings and Recommendations sections.

APHIS stated that its current system of performance-based regulatory standards for notifications is effective at protecting American agriculture. We believe that these performance-based regulatory standards do not preclude submission of protocols to APHIS prior to approval of the field test. By not obtaining copies of the protocols, APHIS is relinquishing its

regulatory responsibility in favor of self-certification by the notification applicants—namely, the applicants merely certify in their notification applications that they will meet the performance standards. Further, approved protocols are important control documents that PPQ officers should receive from BRS before they perform an inspection.

Although APHIS disagreed with developing policy guidelines for restricting public access to field tests of edible regulated GE crops, APHIS' strategic plan states that its mission includes protecting human health and safety. The edible GE crops under APHIS' jurisdiction are regulated and, therefore, we believe that access should be controlled. Edible regulated GE crops cannot be grown without restrictions and should not be available even for unauthorized human consumption, while still regulated.

Although two APHIS units, BRS and PPQ, share responsibility for inspections of field test sites, BRS is responsible for the overall inspection process. However, under the current site selection process, once BRS has selected a notification or permit for inspection PPQ is then allowed to choose the specific inspection site. The National Academy of Sciences states that risks must be assessed according to the organism, trait, and environment. Thus, the environment is an important risk factor which BRS should use in the selection of field sites for inspection to ensure that the highest risk sites are always selected.

The following are some comments on the rebuttal (Bradford et al., 2005a) to my critique (Schubert, 2005) of a manuscript (Bradford et al., 2005b) that appeared in Nature Biotechnology. In their original article, Bradford and colleagues argue that the regulation of transgenic food crops should be reduced or eliminated, based upon the assumption that the products of genetic engineering (GE) are no different than those produced by classical plant breeding. I, and hundreds before me, pointed out that this is unambiguously not the case. I used specific references to show that many of their statements were misrepresentations of scientific fact. In their reply to my comments they used several new rhetorical techniques in addition to the standard ones such as taking statements out of context and misquoting sources.

Of greatest concern is the new lexicon that has been evolving in the plant biotechnology industry over the last decade in order to deceive the less technically educated into believing that there should be no concern about GE food crops because, as they argue, the outcomes are identical to those obtained with standard breeding techniques. Since they cannot ignore the overwhelming evidence that GE is highly mutagenic, they are instead trying to equate GE with normal breeding by redefining the fundamental meaning of some relevant terminology.

An excellent book entitled "Genetically Modified Language", written by a linguist, Guy Cook, shows how the plant biotechnology community is misusing language to promote themselves (Cook, 2005). As described in detail below, examples of "genetically modified language" are abundant in the rebuttal by Bradford et al. of my critique.

1. Lack of precision. The initial response of Bradford et al. in defense of the unambiguously high rate of mutagenesis in GE crops is a perfect example of how plant biotechnology is attempting to change the technical definitions of genetics for the purpose of self promotion. They state that "conventional breeding is based on essentially random induction or assembly of mutations", followed by "imprecise natural recombinations between genomes". Thus, they are equating recombination with mutagenesis, and so, by extension, GE with natural breeding. This is not only scientifically incorrect but exceptionally deceptive.

Recombination occurs with high fidelity between allelic genes. There is no mutagenesis involved in the standard recombination event, for if there were, there would be no such

thing as a stable species of plant or animal. This section of the critique by Bradford et al. concludes by stating "changes accompanying GE may occur, but are irrelevant so long as the expected phenotype is produced". The problem here is that they redefine phenotype to suit their purposes. In general scientific usage phenotype refers to all traits, while these authors use 'phenotype' in both their original paper and their rebuttal to mean solely agricultural characteristics, ignoring other traits that might be caused by genotypic changes from GE. The tests used to assay unintended changes to phenotype are, to date, quite limited. The legitimate debate is whether these limited tests are adequate. Will an assay to detect changes in yield of peas detect an increase in rotenone or other harmful secondary metabolites?

2. Basic research vs. cultivar development. The discussion in this section is completely meaningless, for in my critique I was concerned about toxicological traits, not agronomic ones, and unless they can establish a causal link between plant height or yield and potentially toxic secondary metabolites, agronomic traits are not relevant to the health and safety issue.

3. Mutagenized cultivars. Since both the original Bradford paper and my critique deal only with US regulatory policies, I specifically stated that I was discussing food crops in the US. The manuscript by Ahloowalia et al. (Ahloowalia et al., 2004) lists all of the registered crops (non-food as well as food) in the world that have a mutagenized parent. The "2,275 varieties of 175 species" referred to by Bradford et al. include flowers and many other non-food crops, and the vast majority are not now and never were used commercially. As I stated in my critique of the food crops, the only one listed by Ahloowalia et al. as a commercial crop in the US is the sunflower. The major cultivars of the US crops of corn, soybeans and wheat are not derived by mutagenesis. The implication that I misrepresented the Ahloowalia article is therefore incorrect. Indeed, it would be of interest to many if Bradford et al. could list and document those vast numbers of crops in the US food supply that they claim are derived by mutagenesis.

4. Wide crosses. I agree that "genetic changes often accompany wide crosses". I don't doubt that genetic changes always occur during any breeding procedure. Indeed, that is the point of sexual reproduction. However, the question is whether or not those changes that do occur are the same as those caused by GE? First, Bradford et al. again try to

equate recombination with mutagenesis which, as discussed above, is not correct. Knowing this group's propensity for "genetically modified language" I specifically pointed out the difference in my original critique. Second, their "large body of evidence" supporting the claim that wide crosses are mutagenic is rather paltry, and certainly does not justify all of the claims that they make for genomic modifications outside of changes in copy number and recombination, which are not mutations. For example, the cited paper by Madlung et al., 2005 used to support their claims of naturally occurring transposition in fact only shows that in *Arabidopsis* polyploids there is "transcriptional activity of several transposons although their transposition was limited" (Madlung et al., 2005). In other words, some transposon-dependent RNA was made, but it did not reverse transcribe and randomly insert into the chromosomal DNA to cause mutations (as occurs with GE manipulations). Both Madlung et al. (2005) and Liu & Wendel (2000) show that changes in DNA methylation at sites within or flanking the normally inactive transposons are responsible for their "limited" or "ephemeral" activation. While both papers show that transposons can transiently be transcribed, neither established that DNA products were made and incorporated into functional DNA, thereby possibly causing a mutation. Furthermore, the "silenced genes" in the cited manuscripts are in fact the transposons, and gene silencing is not a mutagenic event (half of the X chromosome complement in human females is silenced by methylation).

Again, aside from wheat, not a single one of the cited manuscripts showed that wide crosses produced mutations. In wheat allopolyploidization does cause the elimination of blocks of DNA and transient retrotransposition (Levy & Feldman, 2004). However, tetraploid wheat occurred about 500,000 years ago and hexaploid about 9500 years ago. Synthetic allopolyploid wheat has been made in the laboratory, but I am not aware of any commercial crops from this material.

5. Promoters. My comments have nothing to do with promoters, either viral or genomic, per se, but only with the fact that in GE plants they are used in synthetic DNA constructs to drive the expression of foreign genes in all plant tissues, and that this is by no stretch of fact or imagination a situation that occurs in nature.

Plant biologists are very defensive about this aspect of their technology, and as witnessed here they try to talk their way around it by presenting information unrelated to the expression of foreign genes in all tissues.

While I did not express any particular concern about the transfer of antibiotic resistance from GE plants to animals, it must be pointed out that contrary to the views expressed by plant biologists, it has clearly been shown that a transgene from GE soya can survive passage through the small intestine and can transfer its DNA to the microflora of the small intestine (Netherwood et al., 2004).

Although the gene was a fragment of the glyphosate resistance gene from soybeans, there is no reason why other genes could not also transfer. Therefore there is horizontal gene transfer from plant material to gut bacteria and if for some reason there is a selective advantage for those bacteria expressing the gene (for example, during a course of antibiotics), they could become the dominant population within the gut. Since plant DNA also can be taken up by and integrated into the cells lining the intestines and other tissues (Einspanier et al., 2001; Schubbert et al., 1994; Schubbert et al., 1997; Schubbert et al., 1998), the possible health consequences of this transfer cannot be ignored.

While I agree that antibiotic resistance may not be an issue for the common antibiotics like ampicillin and tetracycline, as pointed out by Bennett et al. (2004) "bacterial AR genes that are uncommon in bacterial pathogens, and for which any further spread would be undesirable, if not disastrous, should not be used as marker genes in GE plant development". Curiously, one of the papers cited by Bradford et al. is an attempted justification by a group sponsored by Monsanto to do exactly that - introduce kanamycin resistance into GE plants as a selectable marker (Flavell et al., 1992).

6. Transposition. Again Bradford et al. redefine scientific terminology to obscure the facts. In their statements, they explicitly equate the expression of mRNAs with the insertion of reverse transcribed DNA into genomic DNA (transposition). I state that there is no transposition, not that some plants (and animals) cannot occasionally transcribe some mRNA from these repetitive elements. It is possible that I have missed published data showing that transposition does occur in non GE food crops, but if this is the case,

the appropriate reference should have been cited by Bradford et al. Thus they either do not understand the science or are purposely misrepresenting the data.

7. Screening. The statement that "humans have adapted to diverse plant chemistries" is curious in that it states exactly the opposite of the true situation and is one of my major concerns about GE. Human physiology did not evolve to fit that of plants and there certainly would be no selection against the ingestion of compounds with long-term consequences such as carcinogens.

Instead, for the last 10,000 years, humans have selected and bred plants that did not make them sick and promoted their health. Bradford et al. contend the opposite. Since, as Roessner et al. (2001) clearly demonstrate, new chemicals not found in conventionally produced plants are indeed made by GE plants, it would be very naive to think that humans can "adapt" to all new plant metabolites. Humans are obviously not too good at adapting to rotenone or cyanide, both of which have been present in plants for thousands of years. Since GE can lead to the introduction of novel compounds, 10,000 years of experience with food safety is essentially disregarded by the promoters of GE.

The cited Ames & Gold paper (1997) has nothing to do with the normal consumption of plants and their metabolites. Instead it argues that animals fed almost any "pure" chemical at high enough doses to cause tissue damage will develop cancer due to the increased rate of cell division required for tissue repair, increasing the probability of cell transformation. Aberrant mitogenesis is a major cause of cancer in the developing world due to chronic infections and tissue lesions.

The argument that metabolic profiling would lead to chaos is ridiculous, for it would only have to be done with the few cultivars that are intended for production (the finalists in any given breeding program) and only needs to identify molecules that are toxic or novel. The real reason that the plant biotech companies do not want to do this or any other testing is because they fear potentially hazardous compounds will be detected.

With respect to the extensive quotation from the two co-authors on the Kuiper paper (2001) who supposedly changed their minds on the metabolic profiling issue, it should be pointed out that neither are the senior or corresponding authors on either paper and

that they now work for a biotech company as opposed to the unbiased government health agency when they were co-authors on Kuiper's manuscript.

Finally, the comment about 3% of insertions leading to "visible phenotypes" says nothing about the invisible ones related to secondary metabolism, and the comment about the plant's ability to "buffer" itself against genetic changes is only minimally true and says nothing about what the plants are making in the way of compounds that have no visible phenotype, such as secondary metabolites.

Furthermore, plant defense compounds, which are of special concern because they are often also harmful to people, have been shown to be particularly susceptible to change (Schwab, 2003). This makes sense because they have to adapt to co-evolving pests, and this argues against effective buffering for classes of compounds that are of particular concern as toxins and allergens.

8. Unintended changes. I cite two independent papers by academic scientists showing that lignin levels are elevated in Bt corn and soybeans (Saxena and Stotzky, 2001; Gertz et al., 1999), while Bradford et al. cite one paper published in an agricultural trade journal funded by the Agricultural Biotechnology Stewardship Technical Council claiming that the original papers are incorrect (Jung and Shaeffer, 2004). Contrary data may have many explanations, such as subtle differences in methodologies or measuring somewhat different parameters. This is a common tactic that biotech promoters use frequently to counter any published data that is unfavorable to their industry.

9. Mutagenicity tests. The Ames test is a valid reflection of mutagenicity and potential carcinogenicity of compounds, and is required for approval for all drugs, cosmetics and chemicals that are released into the environment. It is simple (I have had a 7th grade student run the assays in my laboratory) and very cheap. It is used widely in many parts of the world to test plant products before giving them to humans (Ribnicky et al., 2004; Chen et al., 2003). The "high-dose test" is miscited by Bradford et al. and is not relevant to the issue of food safety, for only plant extracts need be tested. It is clear from the comments of Bradford et al. that they do not understand the Ames test or how it is used in other countries to screen plants and plant extracts.

SUMMARY

The response of Bradford et al. to my critique of their article that argued for further reductions in the regulation of GE food crops is typical of GE promoters in that it is both misleading and does not correctly represent the facts. For example:

1. The biotech industry misuses language to redefine scientific terms in order to make the GE process sound similar to conventional plant breeding. Examples from Bradford, et al. include equating recombination with mutagenesis and calling the expression of mRNA from transposons transposition.
2. There is a lack of understanding of elementary biology when it is stated that humans have adapted to plant secondary metabolites rather than humans having selected non-toxic cultivars, as well as the belief that the Ames test is done in animals.
3. I focused my critique on food crops and the GE process, while Bradford et al. frequently cited work with flowers and other non-food crops, but did not state this in their text.
4. Papers were conveniently left out that showed the opposite of their claims. For example, the Netherwood paper that shows horizontal GE gene transfer between ingested plants and gut bacteria.
5. Their definition of phenotype in their original paper is extremely simplistic. It includes only basic agricultural properties. This is a convenient mechanism that allows them to ignore problems associated with more subtle and potentially more dangerous unintended effects.
6. Both Bradford et al. and I failed to point out that the unintended effect of a specific transgene may be directly correlated with transgene expression, not random mutagenesis as assumed (Roessner et al 2001; Gurian-Sherman, 2004).
7. Perhaps the most curious aspect of all is that plant biotechnology is complaining about a regulatory system that was written by their lawyers (Eichenwald et al., 2001) and at least with respect to the FDA is voluntary and lacks safety testing requirements altogether (Gurian-Sherman, 2003; Freese & Schubert, 2004). Although they have what they asked for, they are still complaining about it.

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