

For the Environmental Committee
February 22, 2012

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*Ledge Light Health District
Policy Statement*

Submitted by:
Robert Burns, Board of Directors
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Whereas food is a fundamental prerequisite to human life; and

Whereas the inalienable right to choose the foods we consume is confounded by the absence of labels identifying Genetically Modified Foods; and

Whereas Ledge Light Health District places the highest value on promoting informed, educated and knowledgeable consumers;

Therefore be it resolved:

The Ledge Light Board of Directors supports efforts to require that all food products shall be labeled to reflect that the food has been altered, grown or processed as a "Genetically Modified Food".

ALLIANCE FOR BIO-INTEGRITY

*Preserving the Safety of Our Food, the Health of Our Environment,
and the Harmony of Our Relationship with Nature*

WHY THE FDA'S POLICY ON GENETICALLY ENGINEERED FOODS IS IRRESPONSIBLE AND ILLEGAL

Steven M. Druker
Executive Director

Genetically engineered foods are on the market *only* because the U.S. Food and Drug Administration (FDA) has covered up the warnings of its own scientists, misrepresented the facts, and violated explicit mandates of U.S. law. The following points provide the details.

1. The Food Additive Amendment of the U.S. Food, Drug and Cosmetic Act institutes a precautionary approach and mandates that new additives to food must be demonstrated safe before they are marketed. 21 U.S.C. Sec. 321
2. An official Senate report described the intent of the amendment as follows: "While Congress did not want to unnecessarily stifle technological advances, it nevertheless intended that additives created through new technologies be proven safe before they go to market. (S. Rep. 2422, 1958 U.S.C.C.A.N. 5301- 2 *emphasis added*)
3. Although the FDA admits that the various genetic materials implanted in bioengineered organisms are within the amendment's purview, it claims they are exempt from testing because they are generally recognized as safe (GRAS).
4. However, the FDA's regulations state that substances added to food that were not in use prior to 1958 cannot qualify as GRAS unless they meet two requirements. Not only must they be acknowledged as safe by an overwhelming consensus of experts, but this consensus must be based on "scientific procedures" – which ordinarily entails studies published in peer-reviewed journals. (21 CFR Sec. 170.30 (a-b))
5. FDA regulations further stipulate that there is no reduction of evidentiary burden in the case of GRAS substances and that they "...require the same quantity and quality of scientific evidence as is required to obtain approval of the substance as a food additive." (21 CFR Sec. 170.30(b)) Thus, it's clear that the GRAS exemption is not intended to excuse lack of testing but rather to relieve a producer from performing new tests for substances already known to be safe on the basis of previous ones.
6. Genetically engineered foods fail both requirements. There is substantial dispute among experts about their safety, and none has been confirmed safe through adequate testing.

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7. As the FDA was developing its policy on GE foods during 1991- 92, there was not even consensus of safety among its own experts. The predominant opinion was (a) that these new foods entail unique risks, especially the potential for unintended harmful side effects that are difficult to detect and (b) that none can be considered safe unless it has passed rigorous tests capable of screening for such effects. These scientists expressed their concerns, and warnings, in numerous memos to superiors – memos that only came to light in 1998 when the Alliance for Bio-Integrity initiated a lawsuit that forced the FDA to divulge its files, enabling us to post photocopies of 24 key documents on our website.
8. For example, microbiologist Dr. Louis Pribyl stated: "There is a profound difference between the types of unexpected effects from traditional breeding and genetic engineering" He added that several aspects of gene- splicing "... may be more hazardous . . ." (#4 in the set of photocopies of FDA memos at www.biointegrity.org/list.html . Numbers after subsequent quotes from FDA scientists refer to the document number in this set.) Similarly, Dr. E.J. Matthews of the FDA's Toxicology Group warned that "... genetically modified plants could ... contain unexpected high concentrations of plant toxicants..." and he cautioned that some of these toxicants could be unexpected and could "...be uniquely different chemicals that are usually expressed in unrelated plants." (2) Citing the potential for such unintended dangers, the Director of FDA's Center for Veterinary Medicine (CVM) called for bioengineered products to be demonstrated safe prior to marketing. He stated: "... CVM believes that animal feeds derived from genetically modified plants present unique animal and food safety concerns." (10) He explained that residues of unexpected substances could make meat and milk products harmful to humans. And the head of the Biological and Organic Chemistry Section chided agency bureaucrats for turning prior policy "on its head" in attempting to equate GE foods with their conventional counterparts. He also pointed out that lack of proof a GE food is dangerous does not assure its safety, noting that "in this instance ignorance is not bliss." (7)
9. In light of these unique risks, agency scientists advised that GE foods should undergo special testing. For instance, the Division of Food Chemistry and Technology cautioned, "... some undesirable effects such as ... appearance of new, not previously identified toxicants ... may escape breeders' attention unless genetically engineered plants are evaluated specifically for these changes. Such evaluations should be performed on a case-by-case basis, i.e., every transformant should be evaluated before it enters the marketplace." (6) These experts advised the evaluation should include toxicological tests.
10. The pervasiveness of the concerns within the scientific staff is attested by a memo from an FDA official who protested 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." She declared: "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 memo of 1/8/92. *FDA Document #1*)

11. Moreover, FDA officials knew there was not a consensus about the safety of GE foods among scientists outside the agency either. For instance, FDA's Biotechnology Coordinator acknowledged in a letter to a Canadian health official that there is no such consensus in the scientific community at large. He also admitted, "I think the question of the potential for some substances to cause allergenic reactions is particularly difficult to predict." (Dr. James Maryanski letter of 10/23/91. *FDA Document #8*)
12. Nevertheless, the agency's decision-makers – who acknowledge they have been operating under a policy "to foster" the U.S. biotechnology industry – covered up the warnings and admissions of their staff, professed themselves "not aware of any information" showing that GE foods differ from others "in any meaningful way," and allowed GE foods to be marketed without any testing by claiming there is an overwhelming consensus among experts they are safe. ("Genetically Engineered Foods," *FDA Consumer*, Jan.- Feb. 1993, p.14; *Statement of Policy: Foods Derived From New Plant Varieties*, May 29, 1992, Federal Register vol. 57, No. 104 at 22991.)
13. The FDA persists in its claim that there is overwhelming expert consensus that GE foods are as safe as others, even though (a) its own experts clearly held otherwise and (b) it has repeatedly been alerted through formal channels that numerous eminent scientists outside the agency also view these foods as riskier than conventional ones.
14. This lack of consensus in itself disqualifies GE foods from GRAS status. But even if consensus did exist, no GE food would qualify as GRAS because none has satisfactorily passed the level of testing that the law requires – and that the FDA experts stated is necessary. The FDA does not require any testing, and the tests relied on by regulators in the EU and elsewhere do not adequately screen for the unexpected side effects about which the FDA scientists warned. The inadequacy of current testing has been pointed out by numerous experts, including the Royal Society of Canada and the Public Health Association of Australia.
15. Thus, although the "generally recognized as safe" exemption was intended to permit marketing of products whose safety has already been demonstrated to the scientific community through sound testing, the FDA is now using it to circumvent testing and to approve novel products based on mere presumptions that are dubious in the eyes of its own as well as numerous other experts. To achieve its aim, the agency has resorted to systematic misrepresentation, and its false claim about consensus continues to serve as the *sole* purported legal basis for the presence of GE foods on the U.S. market.
16. New laws are not needed in order for the FDA to properly regulate GE foods. The existing law is quite strong and more than adequate. The problem is not lack of a proper law but the FDA's chronic refusal to follow it.

The following paragraphs more fully document the extent of the FDA's malfeasance.

A. Addressing the extensive death and disability caused by a GE food

In 1989, the Japanese manufacturer Showa Denko K.K. began marketing a food supplement of the amino acid L-tryptophan that was produced with genetically engineered bacteria. As part of the process, several genes to substantially increase the output of tryptophan were spliced into the

bacterial DNA. Within a few months of entering the U.S. market, the bioengineered supplement caused an epidemic of an unusual malady (called EMS) that resulted in the deaths of dozens of people and the permanent disability of at least 1,500 others.

For many preceding years, other manufacturers had marketed food grade L-tryptophan supplements produced from bacteria without use of gene-splicing. Epidemiological evidence from the Center for Disease Control does not link any tryptophan from these other manufacturers with outbreaks of EMS. (Kilbourne, E. *Journal of Rheumatology Supplement*, vol. 46, Oct. 1996) Further, Showa Denko's bioengineered tryptophan was found to contain numerous contaminants, at least two of which were novel and had not been seen in any of those conventionally produced batches. It is still not known which contaminant (or combination of them) caused the epidemic.

Although there is no conclusive proof that EMS resulted from genetic engineering, the link has not been ruled out; and many experts think that whatever toxin caused the disease could have been an unexpected side effect of the gene-splicing procedure. The main reason a definitive answer has not been reached is that the relevant evidence in Showa Denko's laboratory was destroyed before it could be examined.

In private, FDA officials confirm that the bioengineering process might have caused the EMS. On September 27, 1991, Dr. James Maryanski, Coordinator of FDA's Biotechnology Working Group, was questioned by staff of the GAO. According to his record of the meeting: "I said that we have no new information, that we do not yet know the cause of EMS nor can we rule out the engineering of the organism." *Emphasis added.* (FDA Administrative Record at 22,923) When I questioned him in private eight years later, Dr. Maryanski again admitted that bioengineering cannot be ruled out. (*Personal conversation*, Washington, D.C. November 30, 1999)

FDA's Public Response: On July 18, 1991, Dr. Douglas L. Archer, Deputy Director of FDA's Center for Food Safety and Applied Nutrition (CFSAN), testified before the House of Representatives Subcommittee on Human Resources and Intergovernmental Relations about the L-Tryptophan tragedy. He said the incident confirmed the FDA's warnings about the hazards of many health food supplements and that the deaths and injuries "demonstrate the dangers inherent in the various health fraud schemes that are being perpetrated on segments of the American Public." Dr. Archer's prepared remarks never indicated that the toxic batches of L-Tryptophan had been produced through genetic engineering, nor did he once raise the possibility it was this process rather than any presumed problems with L-Tryptophan supplements in general that was the cause of the illnesses.

The FDA and other agencies of the federal executive branch continue to cloud the fact that the fatal L-Tryptophan was derived through bioengineering and persist in claiming that no GE food has been associated with a human health problem. For instance, in September 1999, David Aaron, U.S. Deputy Secretary of Commerce, declared, "Not a rash, not a sneeze, not a cough, not a watery eye has been developed from this [GE foods], and that's because we have been extremely careful in our process of approving them." (*Reuters*, September 16, 1999)

B. Addressing the use of antibiotic resistant marker genes

Because most cells subjected to gene implantation techniques fail to incorporate the foreign gene, a large number must be used, and a marker must be attached to the foreign gene in order to identify the cells that have taken it up. The manufacturers decided that genes coding for

resistance to anti-biotic chemicals would be the most economical markers. They especially desired to use a gene that confers resistance to kanamycin, a broad-spectrum antibiotic with a significant medical use. On September 30, 1992, FDA's Biotechnology Coordinator requested the Division of Anti-Infective Drug Products to evaluate the proposed use of the kanamycin resistance marker gene. (11) On December 3, 1992, the Division's experts submitted their written opinion. To emphasize their concern, they capitalized all the letters in the key sentence of their conclusion: "IT WOULD BE A SERIOUS HEALTH HAZARD TO INTRODUCE A GENE THAT CODES FOR ANTIBIOTIC RESISTANCE INTO THE NORMAL FLORA OF THE GENERAL POPULATION." *Emphasis in original* (12) In sending the document to another FDA official, the Division's director included a cover letter titled, "The tomatoes that will eat Akron." (The first commercial use of the marker was planned for a GE tomato.) He said: "You really need to read this consult. The Division comes down fairly squarely against the kan gene marker in the genetically engineered tomatoes. I know this could have serious ramifications." (12)

On March 30, 1993 the Division's Supervisory Microbiologist sent a follow-up memo to the Biotechnology Coordinator in which he strongly criticized the proposed use of the marker. He noted that although other markers are available, industry prefers the anti-biotic resistant ones because they are more economical. He stated that to make the choice on this basis was wrong, considering the risks involved: "In my opinion, the benefit to be gained by the use of the kanamycin resistance marker in transgenic plants is out weighed by the risk imposed in using this marker and aiding its dissemination nation wide. If we allow this proposal, we will be adding a tremendous quantitative load of genetic material to the environment which will probably assure dissemination of kanamycin resistance." (13)

FDA Response: The agency approved the use of the kanamycin resistance gene not only in tomatoes but in other vegetables as well. Consequently, most GE foods now contain anti-biotic resistance genes.

C. Addressing the tests on the "Flavr Savr" tomato

The first GE whole food that the FDA reviewed was Calgene's "Flavr Savr" tomato. Although the FDA did not require testing, Calgene voluntarily subjected the tomato to animal feeding studies and asked the agency to review the data. FDA scientists noted a pattern of stomach lesions that raised a safety issue. Further, seven of the rats fed one variety of the GE tomato died within two weeks. Commenting on the data, Dr. Robert J. Scheuplein, director of the FDA's Office of Special Research Skills, wrote: "... the data fall short of 'a demonstration of safety' or of a 'demonstration of reasonable certainty of no harm' which is the standard we typically apply to food additives. To do that we would need, in my opinion, a study that resolves the safety question raised by the current data." (15) Dr. Carl B. Johnson of the Additives Evaluation Branch concurred that "... unresolved questions still remain." (16)

It is noteworthy that FDA officials had instructed their experts to apply a *lower* safety standard in evaluating the tomato than the standard used for new food additives. (*Scheuplein memo*, p.4) In doing so, they violated the FDA's own regulations, which (as earlier noted) mandate that even foods claimed to be GRAS "...require the same quantity and quality of scientific evidence as is required to obtain approval of the substance as a food additive." (21 CFR Sec. 170.30(b))

FDA Response: The agency claimed that all relevant safety issues had been satisfactorily resolved and said that because the Flavr Savr had performed so well, it would be unnecessary for any subsequent bioengineered food to be subjected to the same standard of testing. To date, there is no reliable evidence showing that any has satisfied the standard the Flavr Savr failed to meet.

D. What the FDA says in public

In addition to the false statements noted in the previous sections, the agency has continued to misrepresent the facts. For example, on February 28, 2000, Dr. James Maryanski, the agency's primary spokesperson on GE foods, responded to revelations in the British press about the memos in the FDA files while addressing the OECD Conference on GE Food Safety in Edinburgh, Scotland. He stated that the staff scientists had merely been "asking questions" about the various issues involved in bioengineered food. But as their own memos clearly indicate, they were making declarative statements, many of them quite emphatic, about the unique potential of bioengineering to induce unintended and unpredictable negative side effects. Further, on May 3, 2000, the FDA Commissioner declared: "FDA's scientific review continues to show that all bioengineered foods sold here in the United States today are as safe as their non-bioengineered counterparts." Yet the year before, the FDA acknowledged it does not perform substantial reviews of GE foods, stating: "FDA has not found it necessary to conduct comprehensive scientific reviews of foods derived from bioengineered plants ... consistent with its 1992 policy." (Reported in *The Lancet*, May 29, 1999) Moreover, as previously pointed out, the most extensive test it did review (on the Flavr Savr tomato) raised a safety issue that, according to its own experts, was never resolved.

E. The FDA has an agenda to promote the U.S. biotech industry

The FDA's acknowledged policy "to foster" the U.S. biotechnology industry is part of a broader executive policy that was initiated by the Reagan/Bush administration – and has continued through each successive administration, including Clinton/Gore and Obama/Biden. Further, when in 1991 the FDA created a new position of Deputy Commissioner for Policy to supervise the formulation of its policy on GE foods, it appointed Michael Taylor, a Washington, D.C. lawyer who had been representing Monsanto and other members of the biotech industry on food regulatory issues. During Mr. Taylor's tenure as Deputy Commissioner, references to the potential unintended negative effects of bioengineering were progressively deleted from drafts of the policy statement (over the protests of agency scientists), and the final statement was issued claiming (a) that GE foods are no riskier than others and (b) that the agency has no information to the contrary. (Subsequently, Mr. Taylor was hired by Monsanto as Vice-President for Public Policy.) Moreover, when Vice-President Dan Quayle introduced the FDA's policy statement in 1992, he referred to it as "regulatory relief" for the industry.

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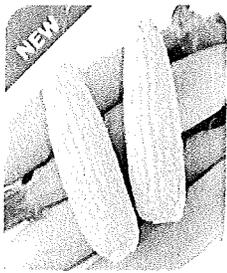


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