

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

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Although most Americans (including those who serve in government) are unaware of it, 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 about their abnormal risks, 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 requires 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)
3. Though 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). (Statement of Policy: Foods Derived From New Plant Varieties, May 29, 1992, Federal Register vol. 57, No. 104 at 22991)
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 these scientific procedures must provide a demonstration of safety and that GRAS substances "...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 supposed to reduce the degree of testing; and the FDA has stated that the only difference between the technical evidence required for a novel substance to be GRAS and the evidence required for it to gain approval via a formal food additive petition is that in the former case, the data must be "generally available (e.g., through publication in the scientific literature)," while in the latter case, it is "privately held."
< <http://tinyurl.com/http-fda-gov-GRAS-Guidance> >
6. Genetically engineered (GE) foods fail both requirements. There is substantial dispute among experts about their safety; and none has been confirmed safe through adequate testing.

7. As the FDA was developing its policy on GE foods during 1991-92, there was not even a consensus among the agency's own experts that these products are safe. Instead, the predominant opinion was (a) that they 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 in numerous memos to superiors – memos that only came to light in 1998 when the lawsuit led by the Alliance for Bio-Integrity forced the FDA to divulge its files. (Copies of these FDA memos are posted at <http://biointegrity.org/24-fda-documents>)

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 . . ." (FDA Document 4 at <http://biointegrity.org/24-fda-documents>) 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." (Document 2 at <http://biointegrity.org/24-fda-documents>) 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* [emphasis added] animal and food safety concerns." (Document 10 at <http://biointegrity.org/24-fda-documents>) He explained that residues of unexpected substances could make meat and milk products harmful to humans.

9. In light of these unique risks, agency scientists advised that GE foods should undergo special testing, including toxicological tests. (e.g. Documents 2 & 6 at <http://biointegrity.org/24-fda-documents>)

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." (Document 1 at <http://biointegrity.org/24-fda-documents>)

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 was 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." (Document 8 at <http://biointegrity.org/24-fda-documents>)

12. 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 agency's files demonstrate that as of 1992, there was virtually no evidence to support safety, with one official's memo to the Biotechnology Coordinator querying: "... are we asking the scientific experts to generate the basis for this policy statement in the absence of any data?"

(Document 1 at <http://biointegrity.org/24-fda-documents>) And the evidentiary base is still sorely deficient because the FDA does not require any testing; and the tests relied on by the EU, Canada, and other governments 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. (*Also see paragraph 27 below.*)

13. Despite the ample evidence indicating a lack of consensus about safety, as well as the lack of requisite evidence to confirm it, the FDA's decision-makers (who acknowledge they've been operating under a policy "to foster" the U.S. biotechnology industry) declared that as long as a GE food doesn't introduce a known toxin or allergen, they would not only presume that it's GRAS, but would even permit it to be marketed without any test-based evidence to establish its safety. In doing so, they professed themselves "not aware of any information" showing that GE foods differ from others "in any meaningful way," even though they had received extensive input from the agency's scientists pointing out the significant differences and their serious implications. (The agency's promotional policy was acknowledgement in "Genetically Engineered Foods," *FDA Consumer*, Jan.-Feb. 1993, p.14. Its fraudulent denial of awareness appears in: *Statement of Policy: Foods Derived From New Plant Varieties*, May 29, 1992, Federal Register vol. 57, No. 104 at 22991)

14. Although many people have been led to believe that the U.S. district court in *Alliance for Bio-Integrity v. Shalala* determined that GE foods are on the market legally, its decision actually highlights the extent to which their presence is contrary to the law. (*Alliance for Bio-Integrity v. Shalala*. 116 F. Supp. 2d 166 (D.D.C. 2000) at p. 179)

15. In her written opinion, the judge stated: "Plaintiffs have produced several documents showing significant disagreements among scientific experts." (116 F.Supp.2d 166 (D.D.C. 2000) at 177) However, although such disagreements entailed that GE foods were not GRAS when the lawsuit was filed in 1998, she ruled that the crucial issue was not whether the products were GRAS at that point in time (or were actually GRAS when the FDA issued its policy statement on them in May 1992), but whether FDA administrators had acted arbitrarily in 1992 in *presuming* that they were GRAS. Therefore, because she held that the case hinged on the narrow procedural issue of whether there had been adequate rational basis for the FDA's presumption, she said that any evidence showing lack of expert consensus at the time of the lawsuit was irrelevant, since it was not within the administrators' purview when they made their presumption in 1992.

16. As for the evidence that had been within the FDA's own files in 1992, she ruled that the administrators were free to disregard the opinions of subordinates when setting policy. (116 F.Supp.2d 166 (D.D.C. 2000) p.178) This conclusion is odd, since the written opinions of the agency's scientists represented far more than mere policy preferences. They constituted solid evidence that a significant number of experts did not recognize GE foods to be safe. Further, the judge failed to mention the fact that the FDA's biotechnology coordinator had admitted there was not a consensus within the scientific community, even though plaintiffs' briefs had emphasized it and cited the relevant document.

17. She additionally disregarded the fact (which had also been clearly pointed out to her) that the FDA's files demonstrated there was insufficient technical evidence about safety to support a presumption that GE foods are GRAS. Although her opinion initially acknowledged that such

technical evidence is legally required, she never returned to the issue – a highly irregular outcome.

18. Therefore, because she ignored so much important evidence, her ruling is very dubious. It's also quite narrow. She did not determine that GE foods are (or ever were) truly GRAS. Nor did she determine that any has been demonstrated safe. She merely held that given the information before them in 1992, FDA officials had not acted arbitrarily in presuming that the foods were GRAS. Further, she emphasized that their presumption is, as a matter of law, "rebuttable." (p.172)

19. This is a crucial point, because even if one believes that the FDA administrators had reasonable basis in 1992 to presume that all GE foods are GRAS, it's obvious that their rebuttable presumption has been clearly and continually rebutted – both by the ever-growing dispute among experts and the ongoing lack of adequate testing.

20. Moreover, the lack of consensus and the lack of evidence are glaringly apparent, as the next seven paragraphs amply demonstrate.

21. In the Alliance for Bio-Integrity lawsuit, nine of the plaintiffs were well-credentialed life scientists (including tenured professors at UC Berkeley, Rutgers, the University of Minnesota, and the NYU School of Medicine) who asserted they did not regard GE foods as safe. As noted in paragraph 15 above, the judge acknowledged we had demonstrated there were "significant disagreements among scientific experts." This in itself established that as of May 1998, GE foods could not be considered GRAS.

22. The following year, the respected medical journal *The Lancet* strongly criticized the presumption that GE foods entail no greater risks of unexpected effects than conventional foods, stating that there are "good reasons to believe that specific risks may exist" and that "governments should never have allowed these products into the food chain without insisting on rigorous testing for effects on health." ([The Lancet, Volume 353, Issue 9167, Page 1811, 29 May 1999](#))

23. In 2001, an expert panel of the Royal Society of Canada issued a report declaring (a) that it is "scientifically unjustifiable" to presume that GE foods are safe and (b) that the "default prediction" for every GE food should be that the genetic alteration has induced unintended and potentially hazardous side effects. ("Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada; An Expert Panel Report on the Future of Food Biotechnology" The Royal Society of Canada, January 2001) In describing the report's criticism of the current approach to regulating GE foods, the Toronto Star stated: "The experts say this approach is fatally flawed ... and exposes Canadians to several potential health risks, including toxicity and allergic reactions." (Calamai, P., "Ottawa Rapped, Expert Study Considered Major Setback for Biotech Industry," Toronto Star, February 5, 2001)

24. The British Medical Association has also expressed reservations about the safety of these novel products. As described in the British Medical Journal, the Association released a 2004 report stating that "more research is needed to show that genetically modified (GM) food crops and ingredients are safe for people and the environment and that they offer real benefits over traditionally grown foods." (Kmietowicz, Z. "GM Foods Should Be Submitted to Further Studies, says BMA," [British Medical Journal, 2004 March 13; 328\(7440\): 602](#))

25. In January 2015, a peer-reviewed journal published a statement signed by more than 300 scientists asserting that there is not a consensus about the safety of GE foods and that their safety has not been adequately demonstrated. (Hilbeck et al. *Environmental Sciences Europe* (2015) 27:4. <http://www.enveurope.com/content/pdf/s12302-014-0034-1.pdf>)

26. Thus, the absence of requisite consensus is irrefutable, especially in light of the fact that the FDA has, in court, established that an additive was not GRAS merely by producing testimony from two experts who did not regard it as safe. (*United States v. Seven Cartons . . . Ferro-Lac*, 293 F. Supp. 660, 664 (S.D. Il. 1968)

27. Further, not only has there never been a genuine consensus about the safety of GE foods, the evidentiary base on which such a consensus is legally required to rest has never existed either. This is well-attested by David Schubert, a professor at the Salk Institute for Biological Studies, who recently asserted: “As a medical research scientist who published a comprehensive, peer-reviewed critique of genetically modified food safety testing, I can state confidently that it is false to say such foods and the toxic chemicals they require are extensively tested and proved safe.” ([Letter to the LA Times, October 28, 2012](#))

28. Moreover, although the proponents of GE foods claim that the FDA subjects them to scientific reviews, the voluntary consultations that the agency conducts with the manufacturers are *not* scientific reviews – and the FDA has admitted that they aren’t. As its Biotechnology Strategic Manager has described the process: “The FDA requests that firms submit a summary of their assessment to the agency. The FDA does not request the original data and, therefore, does not conduct a scientific review of the firm's decision.” (Maryanski, J., “Safety Assurance of Foods Derived by Modern Biotechnology in the United States,” July 1996.) In January 1999, the FDA affirmed that it still was not conducting scientific reviews, 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) And this lenient approach is still in place.

29. Although the FDA has been illegally, and fraudulently, exempting GE foods from the testing requirements established by Congress in 1958, hardly any members of Congress are aware of the malfeasance; and the agency continues to deceive them. For instance, although the FDA is well aware of ample information showing that GE foods significantly differ from others, it persists in its bogus claim that it is “not aware” of any; and this blatant falsehood was repeated by an FDA official at a hearing of the Senate Agriculture Committee on October 21, 2015. She also asserted that the consultation process is so “rigorous” that it resolves “all safety issues,” which is not only misleading, but ridiculous, because the process is far too superficial to achieve such certitude.

30. Due to the systematic misinformation, many members of Congress have voted to deny consumers the straightforward labeling of GE foods that the vast majority of them desire. Thus, in July 2015 the House passed a bill that aimed to decisively prevent such labeling. It even sought to exempt GE foods from the safety testing that federal law mandates but that the FDA has illicitly waived. And virtually no one voting “yes” realized that he or she was essentially forgiving the FDA’s flagrant violation of the law – and legitimizing a policy that was deemed both unscientific and risky by the agency’s own experts. Although that bill didn’t reach the Senate in 2015, there will be renewed efforts to block proper labeling in 2016 – efforts which would almost surely fail if the key facts become more widely known.