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

Steven M. Druker, J.D.
President and Executive Director
Alliance for Bio-Integrity

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, misrepresented the facts, and violated explicit mandates of U.S. law. The following points provide the details and describe the solution.

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 (*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 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 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 (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 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 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.

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 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) (*emphasis added*) 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.* 6, 10)

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." (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 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." (8)

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?"(1). And the evidentiary base is still deficient because the FDA does not require any testing; and the tests relied on by the EU, Canada, and others 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.

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 it is legitimate to presume that all GE foods are GRAS – and can therefore be marketed without any testing. In doing so, they professed themselves "not aware of any information" showing that GE foods differ from others "in any meaningful way," despite the extensive input from their scientists pointing out the significant differences and their serious implications. (*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.

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, she ruled that the crucial issue was not whether GE foods were in fact GRAS at the time of the lawsuit (or were actually GRAS when the FDA issued its policy statement on GE foods 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 this 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 formed their policy 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. (p.178) This conclusion seems 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 as safe. Further, the judge did not 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 repeatedly cited the relevant document.

17. Moreover, the judge also disregarded the fact (repeatedly 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. Thus, the judge 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 evidence 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. Regardless of whether one agrees that the FDA administrators had reasonable basis in 1992 to presume that all GE foods are GRAS, it's obvious that this presumption has been clearly and continuously rebutted, both by the ever-growing dispute among experts and the ongoing lack of adequate testing.

20. Consequently, the marketing of GE foods in the U.S. is illegal because none of them is GRAS and none has undergone formal food additive approval. To rectify this situation, the FDA needs to acknowledge the truth, admit that GE foods are not GRAS, and remove them from market. And it must not allow any such product to be re-introduced until it has been confirmed safe through the testing required by law. To do so, the agency does not have to reverse any official determinations, because it has never formally determined that any GE food is GRAS or that any has been demonstrated safe. It merely has to acknowledge that its rebuttable presumption has been solidly rebutted. Otherwise, it will remain in violation of the law – and will continue to deprive Americans of the safeguards that Congress has explicitly mandated.