



# Food Safety *Review*

A PUBLICATION OF THE CENTER FOR FOOD SAFETY

*The Center for Food Safety is a national non-profit membership organization committed to protecting human health and the environment by promoting organic agriculture and other sustainable practices. CFS engages in legal initiatives, grassroots mobilizations, and educational programs designed to influence government and industry and to inform the public on such issues as genetic engineering, food irradiation, and organic food standards.*

## *The Hidden Health Hazards of Genetically Engineered Foods*

A significant percentage of processed foods purchased today contain some genetically engineered (GE) food products.<sup>1</sup> As a result, each day, tens of millions of American infants, children and adults eat genetically engineered foods without their knowledge. Consumers have no way of knowing what foods are genetically engineered because the Food and Drug Administration (FDA) does not require labeling of these products. What's worse, the agency also does not require any pre-market safety testing of GE foods. Companies do not even have to inform the FDA that they are marketing GE foods.<sup>2</sup> The agency's failure to require testing or labeling of GE foods has made millions of consumers into guinea pigs, unknowingly testing the safety of dozens of gene-altered food products.

Not surprisingly, FDA's "no-testing, no labeling" policy is opposed by the vast majority of Americans. The public clearly believes it has a right to know if food has been genetically engineered. Opinion polls consistently show that more than 90% of Americans strongly support the labeling of genetically engineered foods.<sup>3</sup> A 1999 *Time* poll revealed that close to 60% would avoid such foods if they were labeled.<sup>4</sup> And in 1998 more than 275,000 angry consumers protested the Clinton Administration's proposal that genetical-

ly engineered foods be certified as "organic."<sup>5</sup>

Alarmed by the public's overwhelming rejection of GE foods, the biotech industry has recently hired top PR firms and lobbyists in a \$50 million effort to try to sell the public on the idea that GE foods are safe and that they are just like any other food.<sup>6</sup> A centerpiece of the industry PR initiative is their repeated claim that GE foods are subject to rigorous government-mandated testing and have been proven safe.<sup>7</sup> These are outright lies. In 1992, the FDA, without any scientific basis, declared that genetically engineered foods as a class are "generally recognized as safe" and has refused to require any safety testing of any sort for these foods.<sup>8</sup> The

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FDA does not even require notification by companies that they are marketing a genetically engineered food. Nor has the FDA or anyone else proven that GE foods are safe. The FDA, in its response to a lawsuit filed by the Center for Food Safety (CFS) in May 1998, admitted in court that it has made "no dispositive scientific findings," whatsoever, about the safety of genetically engineered foods.<sup>9</sup> In other words, the FDA has given the biotech industry carte blanche to produce and market any number of genetically engineered foods without mandatory agency oversight or safety testing and without a scientific showing that these foods are safe to consume.

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Welcome to the inaugural issue of the *Food Safety Review*. The *Review* is designed to provide the public with accessible, well documented information on important food safety questions. It is often difficult for consumers to obtain dependable information about the food safety issues that are so critical to personal and family health, a sustainable farm economy and the environment. Front page controversies swirl around issues such as genetic engineering, irradiation, sewage sludge, antibiotics, hormones, and pesticides. Yet the mainstream media and government agencies, usually under heavy industry pressure, consistently fail to accurately inform consumers about these issues and, more often than not, disseminate misinformation. Consumers are often left to fend for themselves in a confusing sea of contradictory stories and assertions. The *Review* is intended to be a dependable, independent source of information which will allow consumers to better understand today's cutting edge food controversies. It is our hope that it will allow you to make informed choices about which foods to buy, and that it will help galvanize action on issues critical to our health, the survival of farm communities and the protection of the environment.

The current issue deals with one of the most important and urgent food safety issues before the public — the human health hazards of genetically engineered (GE) foods. The biotechnology industry and the Food and Drug Administration (FDA) have consistently claimed that these foods are safe and have been subject to rigorous government-mandat-

ed testing. Recently the industry announced a massive multi-million dollar PR campaign to assure the public about the safety of GE foods. This issue of the *Review* cuts through the misinformation coming from the industry and government and provides a well documented summary of the numerous potential health hazards presented by these unlabeled, untested foods.

Finally, a note of background on the Center for Food Safety (CFS) which publishes this *Review*. CFS is a non-profit, national membership organization. We attempt to promote awareness and understanding of food safety issues and provide the public — through newsletters, action alerts and our *Review* — with scientifically sound public educational materials. CFS is also the nation's leading legal action group on food safety, utilizing petitions, regulatory proposals and litigation to influence policy makers. You can get updated on our recent legal actions and other initiatives by checking our website at [www.centerforfoodsafety.org](http://www.centerforfoodsafety.org). We also have an interactive website, [www.foodsafetynow.org](http://www.foodsafetynow.org), which enables you to send your comments on GE foods directly to the FDA. If you have not already done so, we hope that after reading this *Review* and becoming more familiar with our activities, you will consider joining CFS as a member. ♡

*Andrew Kimbrell*

## CFS Wins First Round In EPA Lawsuit to Ban Genetically Engineered B.t. Crops

A federal court recently threatened to “hold [the EPA’s] feet to the fire” unless it answers CFS’s charges that its approval of transgenic B.t. crops threatens the future of organic agriculture and risks significant harm to wildlife and the environment. The lawsuit filed by CFS on behalf of itself, Greenpeace and several organic farmers, charges the agency with the “wanton destruction” of *Bacillus thuringiensis* (B.t.), the world’s most important natural pesticide, pointing to warnings by scientists that genetically engineered B.t. crops will lead to insect resistance within 3-4 years. Recent

studies also show that pollen from B.t. corn is toxic to monarch and other butterfly larvae. CFS was forced to bring suit after the EPA failed to respond to its September 1997 petition; however, the EPA has promised U.S. District Court Judge Louis F. Oberdorfer that it will answer the petition by April 2000. For more information or to reference this case, see: Greenpeace Int’l, et al. v. Browner, U.S. District Court for the District of Columbia, Docket No. 99-CV-389 (LFO), filed Feb. 18, 1999. Our pleadings are posted on our website at [www.centerforfoodsafety.org](http://www.centerforfoodsafety.org). ♡

FDA's failure to require safety testing of GE foods could pose a very real health threat to millions of Americans. A significant body of scientific evidence, including findings of FDA's own scientists, shows that the genetic engineering of foods can transform safe foods into dangerous products. Below is a summary of the documented potential human health threats posed by genetically engineered foods. Much of the scientific support for these health hazards has come from the over 44,000 pages of discovery provided to CFS as part of its ongoing lawsuit against the FDA for its failure to require testing and labeling of GE foods.

## Six Potential Human Health Concerns

Genetically engineered foods are different from other foods. Genetic engineering allows, for the first time, foreign genes, bacterial and viral vectors, viral promoters, and antibiotic marker systems to be engineered into food. These genetic "cassettes" are new to the human diet and should be subject to extensive safety testing.<sup>10</sup> Instead, in 1992 the FDA ruled, without any scientific basis, that genetically engineered foods present no different risks than traditional foods.<sup>11</sup> FDA's own scientists ridiculed this unscientific agency view of genetic engineering. "What happened to the scientific elements in [the] document?" one asked.<sup>12</sup> FDA scientists consistently stated that "[t]here is a profound difference between the types of unexpected effects from traditional breeding and genetic engineering. ... [T]his difference should be and is not addressed."<sup>13</sup> What are the new "unexpected effects" and health risks posed by genetic engineering?

### 1 Toxicity

Genetically engineered foods are inherently unstable. Each insertion of a novel gene, and the accompanying "cassette" of promoters, antibiotic marker systems, and vectors, is random. GE food producers simply do not know where their genetic "cassette" is being inserted in the food, nor do they know enough about the genetic/chemical makeup

of foods to establish a "safe" place for such insertions.<sup>14</sup> As a result, each gene insertion into a food amounts to playing food safety "roulette," with the companies hoping that the new genetic material does not destabilize a safe food and make it hazardous. Each genetic insertion creates the added possibility that formerly nontoxic elements in the food could become toxic.<sup>15</sup>

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FDA was well aware of the "genetic instability" problem prior to establishing their no-testing policy. FDA scientists warned that this problem could create dangerous toxins in food and was a significant health risk. The scientists specifically warned that the genetic engineering of foods could result in "increased levels of known naturally occurring toxicants, appearance of new, not previously identified toxicants, increased capability of concentrating toxic substances from the environment (e.g., pesticides or heavy metals)." These same FDA scientists recommended that long term toxicological tests be required prior to the marketing of GE foods.<sup>16</sup>

FDA officials also were aware that safety testing on the first genetically engineered food, the Calgene *Flavr Savr* tomato, had shown that consumption of this product resulted in stomach lesions in laboratory rats.<sup>17</sup> Even more significantly, FDA had already concluded that genetic engineering was a possible cause for the 37 deaths and 1,500 disabling illnesses caused by consumption of the dietary supplement L-tryptophan. Showa Denko, a Japanese company, had begun using genetic engineering to produce the dietary supplement in the late 1980s. It is suspected that the genetic engineering of the supplement created a toxic contaminant by-product which in turn caused the deaths and illnesses.<sup>18</sup>

FDA's response to the potential toxicity problem with genetically engineered foods was to ignore it. They disregarded their own scientists, the clear scientific evidence and the deaths and illnesses already attributed to this problem. The agency refused to require pre-market toxicological testing for GE foods or any toxicity monitoring. FDA made these decisions with no scientific basis and

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without public notice and comment or independent scientific review. The agency's actions can only be seen as a shameful acquiescence to industry pressure and a complete abandonment of its responsibility to assure food safety.

## 2 Allergic Reactions

In the United States, about a quarter of the population reports some adverse reaction to food.<sup>19</sup> At least 8% of children have physically identifiable allergic reactions to food.<sup>20</sup> The genetic engineering of food creates two separate and serious health risks involving allergenicity. The first is that genetic engineering can transfer allergens from foods to which people know they are allergic, to foods that they think are safe. This risk is not hypothetical. A recent study by the *New England Journal of Medicine* showed that when a gene from a Brazil nut was engineered into soybeans, people allergic to nuts had serious reactions to the engineered product.<sup>21</sup> At least one food, a Pioneer Hi-Bred International soybean, was abandoned because of this problem.<sup>22</sup> Without labeling, people with known food allergies have no way of avoiding the potentially serious health consequences of eating GE foods containing hidden allergenic material.

There is another allergy risk associated with GE foods. These foods could be creating thousands of different and new allergic responses. Each genetic "cassette" being engineered into foods contains a number of novel proteins (in the form of altered genes, bacteria, viruses, promoters, marker systems, and vectors) which have never been part of the human diet. Each of these numerous novel proteins could create an allergic response in some consumers.<sup>23</sup> The FDA was also well aware of this new and potentially massive allergenicity problem. The agency's scientists repeatedly warned that genetic engineering could "produce a new protein allergen." Once again the agency's own scientists urged long-term testing.<sup>24</sup> However, the FDA again ignored its own scientists. Because these foods were allowed to be marketed without mandatory testing for this kind of allergenicity, millions of unsuspecting consumers have continuously been exposed to a potentially serious health risk. This FDA action is especially negligent in that the potential consequences of food allergies can include sudden death, and the most significantly affected population is children.

## 3 Antibiotic Resistance

Another hidden risk of GE foods is that they could make disease-causing bacteria resistant to current antibiotics, resulting in a significant increase in the spread of infections and diseases in the human population. Virtually all genetically engineered foods contain "antibiotic resistance markers" which help the producers identify whether the new genetic material has actually been transferred into the host food. FDA's large-scale introduction of these antibiotic marker genes into the food supply could render important antibiotics useless in fighting human diseases.<sup>25</sup> For example, a genetically engineered maize plant from Novartis includes an ampicillin-resistance gene. Ampicillin is a valuable antibiotic used to treat a variety of infections in people and animals. A number of European countries, including Britain, have refused to permit the Novartis Bt corn to be grown, due to health concerns that the ampicillin resistance gene could move from the corn into bacteria in the food chain, making ampicillin far less effective in fighting a wide range of bacterial infections.<sup>26</sup>

For the past seven years, FDA officials have ignored their own scientists' concerns over the antibiotic resistance problem.<sup>27</sup> During the same time, medical professionals around the world have become increasingly alarmed at how GE foods are leading to a massive infusion of antibiotic genes into the human diet. Last year, for example, the British Medical Association (BMA) addressed this problem in its study of GE foods. The BMA's conclusion was unequivocal: "There should be a ban on the use of antibiotic resistance marker genes in GM food, as the risk to human health from antibiotic resistance developing in microorganisms is one of the major public health threats that will be faced in the 21st century."<sup>28</sup>

## 4 Immuno-suppression

Recently, the well-respected British medical journal, *The Lancet*, published an important study conducted by Drs. Arpad Pusztai and Stanley W.B. Ewen under a grant from the Scottish government.<sup>29</sup> The study examined the effect on rats of the consumption of potatoes genetically engineered to contain the biopesticide *Bacillus thuringiensis* (B.t.). The scientists found that the rats consuming genetically altered potatoes showed significant detrimental effects on organ development, body metabolism,

and immune function.<sup>30</sup> The biotechnology industry has launched a major attack on Dr. Pusztai and his study. However, they have as of yet not produced a single study of their own to refute his findings. Moreover, twenty-two leading scientists recently declared that animal test results linking genetically engineered foods to immuno-suppression are valid.<sup>31</sup>

## **5 Cancer**

Along with its approval of GE foods, the FDA in 1993 also approved the use of genetically engineered recombinant Bovine Growth Hormone (rBGH), used to induce dairy cows to produce more milk.<sup>32</sup> At the time the FDA assured consumers that the milk was safe.<sup>33</sup> Recently, however, regulatory bodies in both Canada and Europe have rejected the drug, citing numerous animal and human health concerns.<sup>34</sup> Perhaps of most immediate concern for consumers is that the recent research shows conclusively that the levels of a hormone called insulin-like growth factor-1 (IGF-1) are increased in dairy products produced from cows treated with rBGH.<sup>35</sup> The Canadians and Europeans further found that the FDA had completely failed to consider a study which showed that the increased IGF-1 in rBGH milk could survive digestion and make its way into the intestines and blood streams of consumers.<sup>36</sup> These findings are significant because numerous studies now demonstrate that IGF-1 is an important factor in the growth of breast cancer, prostate cancer, and colon cancer.<sup>37</sup>

## **6 Loss of Nutrition**

Genetic engineering can also alter the nutritional value of food. The genetic instability of these foods (described above) can be a major culprit in reducing their nutrients. In 1992, the FDA's Divisions of Food Chemistry & Technology and Food Contaminants Chemistry examined the problem of nutrient loss in GE foods. The scientists involved specifically warned the agency that the genetic engineering of foods could result in "undesirable alteration in the level of nutrients" of such foods. They further noted that these nutritional changes "may escape breeders' attention unless genetically engineered plants are evaluated specifically for these changes."<sup>38</sup> Once again, the FDA ignored findings by their own scientists and never subjected the foods to mandatory government testing of any sort.

## **A Partial List of Genetically Engineered Foods**

This is a list of processed foods that tested positive for genetically engineered ingredients (September 1999). These tests were not "safety" tests; they were only to establish the presence of unlabeled genetically engineered ingredients.

- **Bravos Tortilla Chips**
- **Kellogg's Corn Flakes**
- **General Mills Total Corn Flakes Cereal**
- **Post Blueberry Morning Cereal**
- **Heinz 2 Baby Cereal**
- **Enfamil ProSobee Soy Formula**
- **Similac Isomil Soy Formula**
- **Nestle Carnation Alsoy Infant Formula**
- **Quaker Chewy Granola Bars**
- **Nabisco Snackwell's Granola Bars**
- **Ball Park Franks**
- **Duncan Hines Cake Mix**
- **Quick Loaf Bread Mix**
- **Ultra Slim Fast**
- **Quaker Yellow Corn Meal**
- **Light Life Gimme Lean**
- **Aunt Jemima Pancake Mix**
- **Alpo Dry Pet Food**
- **Gardenburger**
- **Boca Burger Chef Max's Favorite**
- **Morning Star Farms Better'n Burgers**
- **Green Giant Harvest Burgers (now called Morningstar Farms)**
- **McDonald's McVeggie Burgers**
- **Ovaltine Malt Powdered Beverage Mix**
- **Betty Crocker Bac-Os Bacon Flavor Bits**
- **Old El Paso Taco Shells**
- **Jiffy Corn Muffin Mix**

Sources: Genetic ID (an independent testing firm) and Consumer Reports (September 1999).

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## Conclusion

Much of the current controversy over genetically engineered food surrounds the important issue of labeling. However, the labeling issue is actually a secondary one. The first call to action must be to force the FDA to remove all genetically engineered foods from the market until long-term tests have determined that such foods are safe for human con-

sumption. We do not label unsafe food, we take it off supermarket shelves. Only after proper testing is done, and if the foods are found safe, should they be allowed to be sold. At that time they should also be labeled so those who want to take a precautionary stance, those with allergies, and those who have ethical or religious objections may choose to avoid genetically engineered foods. ♻️

## ENDNOTES

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# In the News

## **CFS files FDA legal petition to force testing and labeling of GE foods**

On March 21, 2000, an unprecedented coalition of more than 50 scientific, consumer, environmental and farm organizations signed onto a legal petition filed with the Food and Drug Administration (FDA) by the Center for Food Safety. This Petition demands that the FDA develop a thorough pre-market and environmental testing regime for genetically engineered (GE) foods and subject all GE foods to mandatory labeling. This critical action, initiated by CFS, successfully united nearly every group working on genetically engineered food issues behind a single coherent set of legal demands. For additional information on this petition or on CFS's ongoing legal case against the FDA on these matters, please visit [www.centerforfoodsafety.org](http://www.centerforfoodsafety.org) or call the Center for Food Safety.

## **GE food legislation introduced in Congress**

Representatives Dennis J. Kucinich (D-OH), Jack Metcalf (R-WA), and a bipartisan coalition of 17 other Members of Congress have introduced the Genetically Engineered Food Right to Know Act (H.R. 3377), legislation which would require that foods that contain genetically engineered material or have been genetically engineered, altered or otherwise modified be labeled as such. Congressman Kucinich and Congressman

Metcalf have also sponsored a bill (H.R. 3883) that would require the pre-market safety testing of all genetically engineered foods. Two pieces of companion legislation have been introduced in the Senate by Senator Barbara Boxer (D-CA); bill S.2080 calls for labeling of GE foods and S.2315 would require safety testing for GE foods.

## **Controversial NAS report on GE foods “hopelessly tainted” by corporate influence**

On April 5, 2000, the National Academy of Sciences (NAS), an organization which purportedly conducts independent scientific investigations, released a controversial study entitled *Genetically Modified Pest Protected Plants*. One hour prior to the release of the report CFS, in partnership with other environmental and consumer groups, held a press conference and rally outside the NAS to voice objections to the pervasive conflicts of interest and corporate influence which tainted the report. Speakers called on the NAS to scrap the report and drew attention to the revolving door that exists between the biotechnology industry and the NAS. Perhaps most egregiously Michael Phillips, the original director of the study was forced to resign midway through the completion of the report after he accepted a position with the Biotechnology Industry Organization. Overall, seven of the study's twelve authors have financial ties to biotech companies, including Monsanto, Novartis, and Pioneer Hi-Bred. ♻

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# Take Action!

## **Save our organic standards! Comment to the USDA today!**

On March 13, 2000, the United States Department of Agriculture (USDA) released a revised proposed rule for the United States National Organic Program. While you may have heard that the rule made some concessions in response to the over 280,000 comments that criticized the shortfalls of the first rule, the “big three” are not dead! The use of genetic engineering, irradiation, and sewage sludge MAY BE ALLOWED because of loopholes in the USDA's prohibition language. Visit [www.foodsafetynow.org](http://www.foodsafetynow.org) to demand that the USDA more clearly define genetic engineering, irradiation, and sewage sludge and classify all three as prohibited, “synthetic” substances, thereby banning them from use in organic agriculture. For a detailed analysis of these issues and

other problems with the Organic Rule, visit [www.centerforfoodsafety.org](http://www.centerforfoodsafety.org) or call the Center for Food Safety today!

## **Pull genetically engineered foods from the market! Comment to the FDA today!**

The Center for Food Safety's legal petition (see “In the News”) demands pre-market safety testing, environmental review and mandatory labeling for all GE foods and food products. As they were required to do by law, the FDA has set up a docket for public response to the petition. IT IS ABSOLUTELY CRITICAL that consumers from across the United States flood the FDA with hundreds of thousands of comments in support of safety testing and labeling of all GE foods. Submit your comments today via our action website, [www.foodsafetynow.org](http://www.foodsafetynow.org) or by writing to FDA Commissioner Jane Henney, 5630 Fishers Lane, Room 1061 (HFA-305), Docket No. OOP-1211/CP 1, Rockville, MD 20852. ♻

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