GE FOODS

GE FOOD & YOUR HEALTH

A significant percentage of processed foods purchased today contain some genetically engineered (GE) food products. 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 U.S. 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. 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.

The FDA, in its response to a lawsuit filed by the Center for Food Safety in 1998, admitted in court that it had made "no dispositive scientific findings," whatsoever, about the safety of genetically engineered foods. 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.

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. Instead, in 1992 the U.S. Food & Drug Administration (FDA) ruled, without any scientific basis, that genetically engineered foods present no different risks than traditional foods. FDA's own scientists ridiculed this unscientific agency view of genetic engineering. "What happened to the scientific elements in [the] document?," one asked. 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."

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. 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.

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, [and] 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. 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.

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 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

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 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. At least one food, a Pioneer Hi-Bred International soybean, was abandoned because of this problem. 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. 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. 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. 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, 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.

Again, FDA officials have ignored their own scientists' concerns over the antibiotic resistance problem. Meanwhile, the British Medical Association (BMA) addressed this problem in its own 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."

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4. Immuno-suppression

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. The study examined the effect on rats of the consumption of potatoes genetically engineered to contain the biopesticide *Bacillus Thuringiensis* (B.t.). Thescientists found that the rats consuming geneticallyaltered potatoes showed significant detrimentaleffects on organ development, body metabolism, and immune function.

The biotechnology industry 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.

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. At the time the FDA assured consumers that the milk was safe. Since then, however, regulatory bodies in both Canada and Europe have rejected the drug, citing numerous animal and human health concerns. Perhaps of most immediate concern for consumers is that research shows 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. 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. 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.

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6. Loss of Nutrition

Genetic engineering can also alter the nutritional value of food. 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." Once again, the FDA ignored findings by their own scientists and never subjected the foods to mandatory government testing of any sort.