APPENDIX 2–B

CONSUMERS UNION COMMENTS ABOUT BIOTECH

The following text is a partial statement of concerns about biotechnology:

Global Trade

Consumers Union (CU) believes it is essential that the FDA process be mandatory so that consumers in the US and trading partners abroad can be assured that all US genetically engineered foods (GE) have completed a safety review. All major transnational corporations marketing GE crops in the US should demonstrate that they have submitted all products for FDA review. If review is voluntary, consumers have no guarantee that developers of GE crops will give full disclosure.

One particular concern is assuring the safety of GE foods imported from developing countries. Increasingly, these countries are developing GE crops in their own laboratories. Many of the crops in the Philippines and Thailand are being grown for the export market. Rice, wheat, corn, papaya, bananas, mangos, coconut, potatoes, tomatoes, peppers, cucumbers, and tobacco are BT grown. China reports 53 transgenic varieties in commercial production or field testing.[1] Iran, Brazil, Mexico, Egypt, South Africa and Malaysia have research programs, but systems for assuring the safety of these crops vary widely.

A comprehensive program for assuring the safety of GE imported food with testing appears warranted and should include requirements that all GE crops developed in any country and sold in the US have an FDA safety review.

The FDA "decision tree" gives latitude to companies to self-evaluate the safety of their GE products. One approach advocated by the Environmental Defense Fund and others is to require GE foods to go through a food additive petition review. This appears reasonable because it would meant that GE foods meet the standard for food additives of "reasonable certainty of no harm."

Source: http://www.consumersunion.org/pub/2000/05/002300print.html

CU recommends that FDA have clear protocols

- for evaluating the known risks of GE foods, including the introduction of toxins, allergens, and nutritional changes
- for identifying any unexpected effects on health and
- for addressing any public health risks such as exacerbation of antibiotic resistance.

Other recommendations are for FDA to

- establish clear benchmarks for how it defines "safety,"
- ...give notice and request comment of its policies,
- strengthen the review system, and
- develop a review system which yields both greater assurance of safety for consumers and more efficient use of FDA resources.

Areas of Concern

The studies which lead to a greater concern about unexpected effects involve:

- unpredictability of the location and expression of transgenic DNA inserts, and
- differences resulting from post-translational processing, e.g., proteins from the same gene are not identical in differing organisms.

With GE or rDNA techniques, one inserts genes on a random basis, using a gene "gun," into a plant's chromosomes. The inability to control where the insertion happens is of key importance. Each transformation event is unique and cannot be replicated because the precise location of the insertion will always vary.

In an experiment involving yeast where genes from the yeast were duplicated and then reintroduced via GE, problems occurred.[2] The scientists found that a three-fold increase in an enzyme in the glycolytic pathway, phosphofructokinase, resulted in a 40- to 200-fold increase of methylglyoxal (MG), a toxic substance which is known to be mutagenic. This unexpected effect occurred even though the inserted genetic material came from the yeast itself. The scientists concluded that the toxic substance may substantiate consumer concerns.

Ewen and Pusztal's very controversial study[3] involved GE potatoes with lecithin to increase resistance to insects and nematodes. Young growing rats fed the potatoes had proliferation of the gastric mucosa.

Questions remain whether foreign DNA can survive digestion in mammals, can be absorbed through the epithelial surfaces of the gastrointestinal or respiratory tract, or be excreted in feces. Ruminant and rat studies in the 1970s[4] and 1980s[5] suggested that DNA and RNA failed to show that DNA survived digestion. In the 1990s, German researchers used very sensitive methods[6] and fed mice DNA. They found 2-4% in feces and 0.01-0.1% in the blood. Sizeable DNA fragments were found at 7 hours after uptake.

Allergies

At an April 1994 conference involving EPA, FDA, and USDA, "Scientific Issues Related to Potential Allergenicity in Transgenic Food Crops," two conclusions

were reached. First, no direct methods exist to assess potential allergenicity of proteins from sources that are not known to produce food allergy, and second, predicting allergenicity of new similar-to-allergen proteins is not 100% assurance.

An earlier Gallup poll found that 68% of consumers want labeling of GE foods even if it increases food costs. When an individual has an allergy to a food, s/he will always react to that food. With a GE food, s/he will react only to the GE variety containing the allergen and not to all varieties of the same food. Labeling it will be exceedingly difficult.

Labels

Labeling recommendations have also included engineered whole food, processed food containing engineered ingredients, and bt foods produced through genetic engineering, such as milk from cows treated with a GE drug. Good record keeping and certification procedures should assist with accurate labeling.

Consumers Union recommended on May 3, 2000, that the label terminology be simple and straightforward, e.g., "contains genetically engineered material" and not promotional, such as, "improved through modern biotechnology." Labeling should be permitted which states that food does not contain genetically engineered material. CU believes FDA should define "not containing" as "not detectable" where current test methodology is available.[7] The current reliable limit of detection appears to be 0.01%; this is the benchmark Consumer Reports used in its testing. Foods containing detectable amounts of GE material should be labeled as such.

References

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