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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Office of Information and Regulatory Affairs, OMB
New Executive Office Bldg.
725 17th St. NW, Rm. 10235
Washington, DC 20503
Attn: Desk Officer for FDA

Dear Sir or Madam:

This letter is written in response to the Request for Comments for Proposed Rule 21 CFR Parts 192 and 592, published in the Federal Register on January 18, 2001. The proposed rule addresses the requirement by the Food and Drug Administration (FDA) of submission of data and information regarding plant-derived bioengineered foods that would be consumed by humans or animals.

Humans have been using breeding techniques to improve the characteristics of cultivated plants and domesticated animals for many centuries. Only in the last two or three decades has the advent of recombinant DNA technology (rDNA) made it possible to go beyond the limitations of cross-breeding and select specific characteristics with great precision and transfer them from one species of plant or animal to a completely unrelated species of plant or animal.

The fact that bioengineered foods have an enormous potential for positive impact on the ability of the world to feed itself is widely accepted. Using rDNA technology to select genes from one plant and insert into another to provide beneficial characteristics can, for instance, increase selected nutritional components in food staples to provide these nutrients to populations that suffer from an overall lack of these nutrients in their traditional diets. For example, experts say that many deaths and many more cases of blindness can be prevented by increasing the levels of beta carotene in the world's diet. Bioengineering technology has produced a modified rice that can provide a rich source of beta carotene that may go a long way in providing this important nutrient to needy populations.

Bioengineered plants may provide benefits in other ways. Genetic modification may give us crops that resist pests, need less nitrogen to grow, and leave less plant material after crop harvest. These improvements will result in the reduced use of pesticides and

fertilizers, and will reduce the need for burning of fields after harvest, all of which would result in lower pollution from these sources.

Along with these positive impacts of bioengineered organisms comes the potential for harm. There are risks associated with the combination of genetic material in ways that are very different from those found naturally. We do not have a great deal of knowledge about the effects of combining traits from several diverse organisms into one organism. Aside from the science-fiction kinds of potential disaster such as rapidly reproducing and uncontrollable organisms, there are a number of reality-based unintended consequences of biotechnology that must be guarded against. These include more the subtle effects of resistance of pathogens to antibiotics, plants that become resistant to herbicides, and the introduction of allergens into previously benign foods.

The heightened worldwide awareness of these potentially harmful unintended consequences is manifested by the highly vocal protests at various biotechnology conferences and by the widespread resistance (particularly in Europe) to the entry of bioengineered foods into the marketplace. It is important that exaggeration of the dangers of biotechnology does not stifle the development and introduction of beneficial organisms into the marketplace.

The FDA's role in this field is two-fold. Primarily, through the Federal Food, Drug, and Cosmetic Act, the FDA is charged with regulating the health and safety of most foods. This gives them wide discretion in determining the appropriate steps necessary to prevent harmful foods from being introduced into the marketplace. A secondary role to be played is maintaining the public's confidence in the safety of the foods available on the market. This is accomplished by maintaining the FDA's credibility as an effective regulator through the prevention of exposure of the public to unsafe foods. This secondary role will be a critical one in the exploitation of biotechnology for the benefit of the people of the United States and the world.

To effectively perform this role in creating confidence in bioengineered foods, the FDA must balance the need to regulate to prevent the introduction of dangerous foods with the needs of the biotechnology industry to be able to bring new products to market at reasonable cost. I believe the regulations as proposed provide this balance through the requirement to submit data on genetic encoding for antibiotic resistance and for possible allergen content of the food.

Three types of sources of danger have been identified for bioengineered plants that may be used as foods. The first involves the unintentional transmission of characteristics through outcrossing. In one scenario, newly introduced genes for resistance to a pest is introduced to second plant through cross-pollination, resulting in the second plant's increased resistance to the pest. This may be a problem if that pest has acted as a natural limitation on the spread of the second plant, and the result is an uncontrolled spread of the plant. Control of outcrossing is most effectively handled by regulation of the introduction of genetically altered plants into the environment rather than by regulation of the food supply, and is therefore best controlled by entities other than the FDA.

The second danger posed by genetically altered plants involves gene transfer. In the laboratory it has been possible to create a spontaneous transfer of genetic material from one source to another via viral transmission. This creates the possibility that some type of immunity in one organism may be inadvertently transferred to a pathogen, creating a pathogen with an artificially high resistance to antibiotics. The proposed regulation addresses this potential source of danger through the requirement in § 192.25(e) of disclosure in the Premarket Biotechnology Notice (PBN) of the existence of genes encoded for resistance to antibiotics.

The third danger posed involves the introduction of allergens into previously benign foods. In one case, a gene from a brazil nut was introduced into soybeans in order to have the soybeans produce sulfur-containing amino acids (in which they are naturally deficient). Exposure to the modified soybeans produced allergic reactions in people who are allergic to brazil nuts, but not to soybeans. The proposed regulation addresses this danger through § 192.25(f)(4) that requires a discussion in the PBM of potential allergens introduced into the food.

One area the proposed regulations do not address directly is the question of labeling. A number of foods that are the result of bioengineering are present in the market now, and are not labeled as such. Although it seems obvious to me that there is a need for labeling these foods in some cases, for instance, when a gene from an allergy-related food is introduced into an allergy-benign food, the argument for labeling in other cases has not been made convincingly on any basis other than the public's "right to know". A broad requirement to label all foods that are the result of rDNA technology would potentially have a dramatic effect on the marketability of these products, and could result in a great reduction in the pace of development of these products. The overall effect would then be overwhelmingly negative, since the many benefits of these products would be delayed or eliminated altogether. The question of labeling is fundamentally a policy question that must be dealt with by Congress.

In conclusion, I am supportive of the FDA's regulations in regard to the requirement of a Premarket Biotechnology Notice to be submitted 120 days prior to a bioengineered product being introduced to the marketplace. The information requirements and process of review adequately balance the legitimate concerns of safety with the needs of the industry to avoid excessive regulatory burdens. I urge you to continue to resist unnecessarily burdensome regulations that are proposed by some radical groups while maintaining the safety of the Amercan food supply.

Sincerely,

Gilbert M. Taylor