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**Comment on "Biotechnology in the Year 2000 and Beyond"**
**[Federal Register Docket# 99N-4282]**

The Organic Materials Review Institute (OMRI) is a non profit organization dedicated to providing professional, independent, and transparent review of materials and compatible processes allowed to produce, process, and handle organic food and fiber. OMRI provides services to 32 organic certification agencies in the United States, including state governmental and private programs. OMRI publishes lists of generic and brand name materials that meet the criteria of the Organic Food Production Act of 1990 as well as recommendations of the National Organic Standards Board for use in organic production and handling. OMRI also provides technical support and educational materials to certifiers and other members of the public interested in organic production and handling. OMRI's subscribing organizations certify as organic over 6,300 individual farms and handlers in the USA. We appreciate the opportunity to comment on FDA's policies and performance regarding "bioengineered foods."

OMRI agrees with the Organic Farming Research Foundation in their analysis that the federal government has fundamentally failed to provide an adequate regulatory regime for transgenic technologies and products. FDA itself describes the major flaw in its own process in the FDA Consumer magazine of January 2000 –"Are Bioengineered Foods Safe?" Dr. Jane Henny notes that FDA oversees food safety regulation, while EPA has jurisdiction for pesticides and APHIS for environmental safety. However EPA is responsible for regulation of plant pesticides, so that leaves quite a gap between the addition of novel toxins and FDA's consideration of safety, which was described simplistically as:

> "If the plant looks normal and grows normally, if the food tastes right and has the expected levels of nutrients and toxins, and if the new protein put into food has been shown to be safe, then there are no safety issues."

EPA obviously missed the environmental consequences of its approval of Bt corn, as evidenced by recent studies documenting the potentially toxic effects of Bt corn pollen on non-target species, and persistance of the transgenic source of the Bt toxin in the soil. OMRI questions whether FDA's approval of the safety of novel plant pesticides is based on adequate animal testing, in view of the fragmentation of responsibilities and the difficulty in obtaining the data supporting such claims.

We agree that there needs to be a comprehensive, accountable, oversight process governing the release of transgenic organisms into the environment and the food supply. Unless and until a new

regulatory system is in place, a moratorium on all transgenic food and agricultural applications should be imposed.

Regarding the six specific issues posed by FDA in its Federal Register notice for this meeting, we have the following comments.

"Scientific/Safety Issues:"
1. [Has FDA's consultation process achieved its intended purpose? Based on experience to date, should this regulatory approach "sunset," continue in its current state, be made mandatory, or otherwise be revised?] This approach should be completely reworked. FDA's so-called "consultation process" has failed to protect the public. Collaboration between government agencies has been wholly inadequate and public has not had sufficient access to crucial information to determine the health and food safety impacts of these foods. The FDA should impose more rigorous requirements for developers to support their claim that their products are no different from food produced by traditional means. The data from the research needs to be open to the public and subject to review by members of the public prior to foods being brought to the market.

2. [What newly emerging scientific information related to the safety of foods derived from bioengineered plants is there, if any? Are there specific tests which, if conducted on such foods, would provide increased assurance of safety for man or animals consuming these foods?]

OMRI considers that the present requirements for animal and human testing of these products are inadequate. New information should be assessed and independent testing required. Of equal or greater concern is the lack of public access to the data and the review of the results of scientific studies.

3. [What types of food products derived from bioengineered plants are planned for the future? Will these foods raise food safety issues that would require different approaches to safety testing and agency oversight? If so, what are those approaches?]

OMRI does not have knowledge of all products under development, and is concerned at the rapid rate that new products are being introduced without adequate notification, labeling, testing, and oversight.

Models that were essentially developed to test the toxicity of static chemical compounds fail to adequately characterize the nutritional and biological impacts of novel live organisms, particularly those that contain functional DNA when consumed either by humans or food-producing animals. By their very nature, bioengineered foods are inherently different. Other safety and health issues, perhaps not as dramatic as acute toxicity but nonetheless of valid concern, are oncogenicity, reproductive effects, and nutritional quality. For example, are the phytoestrogen levels in herbicide tolerant soybeans significantly different from their classically bred counterparts? If so, what are the long-term impacts on food animal and human health? Are there reproductive effects? What are the other implications for recombinant DNA, particularly if it is functional?

It is our opinion that the food safety of bioengineered plants cannot be determined by existing methods, and that new models and methods will need to be developed to address the issues that the FDA raises. These models need to be based more on epidemiology rather than toxicology, and need to have an adequate time horizon and sample size to assess the concerns on an evolutionary and an ecological scale.

Finally, OMRI considers risk assessment methodology to be inherently flawed in protecting public health and food safety in the face of scientific uncertainty. Instead, we urge the Food and Drug Administration to adopt a precautionary model that protects not only the public addressed by this notice, but future generations as well. Given the history and experience with adverse effects caused by the new technology, the scientific uncertainty faced, the prospect of significant harm to the public, and the irreversibility of the outcome, a cautious approach is warranted in regulating bioengineered foods.

Regarding the six specific issues posed by FDA in its Federal Register notice for this meeting, we have the following comments.

"Public Information Issues:"
1. [Should FDA's policy requiring labeling for significant changes, including changes in nutrients or the introduction of allergens, be maintained or modified? Should FDA maintain or revise its policy that the name of the new food be changed when the common or usual name for the traditional counterpart no longer applies? Have these policies regarding the labeling of these foods served the public?]

Organic farmers and processors strive to produce crops and products that do not contain genetically modified organisms or their derivatives. This is clearly demanded by consumers of organic products who rely on the organic label as an indication that the product does not contain genetically modified ingredients. This was made particularly clear when the USDA received over 280,00 comments opposed to the possible allowance of genetically engineered organisms in its proposed rule for the National Organic Program in December, 1997.

OMRI has had experience working with the processors of organic food and their certifiers, and we have found that the current system of labeling is inadequate. Organic food processors have a business interest to know that the minor ingredients that they purchase do not contain any GMOs. Consumers of organic food have demanded of organic certifiers that the food they certify meet that standard. Despite efforts to provide assurance to the public that this standard is being met, organic processed products often contain materials derived from commodities that may be genetically engineered. Organic processors and those charged with regulating organic products are faced with the huge challenge of determining which ingredients and processing aids may come from a genetically engineered source. Even though these ingredients are present in small amounts, they are in widespread use and are very important in processed foods. OMRI is in favor of mandatory labeling of both primary and incidental ingredients and processing aids, as well as all seeds and the products of crops produced from those seeds. Mandatory labeling of such ingredients would provide organic food processors the assurance that they need to be able to source ingredients that meet their product specifications, and provide for sanctions against those who misbrand and make fraudulent claims.

At a minimum, the following groups of ingredients should be labeled if they contain the products of bioengineering or their derivatives: enzymes, amino acids, and cultures of all microorganisms from yeast's to bacteria, starches made from genetically engineered corn or potato, gums, lecithin, citric acid, sweeteners and oils made from genetically engineered crops, vitamins derived from genetically engineered processes, whey and other dairy derivatives made from milk that is a product of cows receiving rBGH.

This is clearly an issue of consumer choice as much if not more than an issue of food safety. Consumers are entitled to make their own choices about food preference, and should have this basic information made available. Marketplace testing has become common when crops are destined for European or Japanese sale, and rejection causing financial hardship due to inadvertent contamination has occurred. In addition to market place concerns, organic producers have grave concerns about the poorly understood impacts of this new technology on the agroecosystem.

2. [Should additional information be made available to the public about foods derived from bioengineered plants? If so, what information? Who should be responsible for communicating such information?]

All data and background information related to safety, efficacy, use and fate in the environment of transgenic food products and ingredients must be provided by the product developers and made available to the public. FDA's decision making process should be documented and described for all approvals of foods derived from bioengineered plants. The developers and marketers of foods produced by GMOs also share a responsibility for communicating information about those products. This most obviously is covered by our support of mandatory labeling, but extends also to information regarding how the organism is bioengineered.

3. [How should additional information be made available to the public: e.g., on the Internet, through food information phone lines, on food labels, or by other means?]

As described above, OMRI feels that FDA should require labeling of all products, including primary and incidental processing aids that are derived from genetic engineering technology. FDA's data should be accessible by every means at its disposal to distribute information to the public and industry. A website modeled on the National Toxicology Program could provide a list of transgenic food products and references to the studies used to support regulatory actions, if not the studies themselves.

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