EMEAC

East Michigan Environmental Action Council

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EMEAC's mission is to protect and restore land, air, water and diversity of life through informed personal and public action

February 13, 2001

FDA Commissioner Jane Henney
Dockets Management Branch (HFA 305)
Food and Drug Administration
5630 Fisher's Lane, Room 1061
Rockville, MD 20852

Dear Commissioner Henney,

Dockets 00N-1396 and 00D-1598

On behalf of the East Michigan Environmental Action Council, I wish to express disappointment that the proposed rule for genetically engineered foods does not require rigorous testing to determine if they are safe for human health and the environment. We believe that genetically engineered food should be tested to the same degree as drugs and food additives.

The failure to require testing assumes that a genetically engineered food plant is substantially equivalent to its conventional counterpart. This is certainly not the case. Genetically modified plants contain genes from other species, often from other biological kingdoms, introduced into a gene pool that evolved quite separately. It is not possible to predict without long term testing the interactions of the transferred genes in the food plant's gene pool. Furthermore, present gene transfer policy is imprecise, so that the expression of the transferred genes cannot be known with certainty. And incorporation of marker genes expressing anti-biotic resistance risks increasing resistance to anti-biotics in humans; already a serious problem. Therefore we believe that the proposed rule gives only the appearance of food safety and might engender a sense of false security among consumers.

In the absence of thorough testing, customers need to be able to distinguish between genetically engineered food and conventional food. They would then be able to make their own decisions whether to accept or reject the potential health risks posed by genetically engineered foods. Consequently, the proposed guidance, which provides for voluntary labeling of genetically engineered food, totally misses the mark. Mandatory labeling should be required; customers have a right to know.

In addition, we should like to draw your attention to an Expert Panel Report on the future of food biotechnology prepared by the Royal Society of Canada at the request of Health Canada, the Canadian Food Inspection Agency, and Environment Canada. This report relates directly to the issues raised by the FDA's proposed rule concerning food developed through biotechnology.

The report contains 57 recommendations that provide a regulatory framework for GM food. It is available on ☐ HYPERLINK

"http://www.rsc.ca/foodbiotechnology/indexEN.html" and is, we believe, well worth your study. The Expert Panel appears to be both dispassionate and disinterested. It concludes, in a nutshell, that the use of the concept of "substantial equivalence" as a decision threshold tool to exempt GM agricultural products from rigorous scientific assessment is scientifically unjustifiable. The panel recommends instead use of the "precautionary principle".

Relative to the guidance the FDA proposes on labeling GM foods, the Expert Panel discussed labeling, although this was not part of its brief, and recommended voluntary labeling would be justified from a scientific point of view. You will recognize, of course, that this recommendation would assume implementation of a complete and rigorous testing regime consistent with the "precautionary principle" and its other recommendations.

The Expert Panel also provided recommendations on appropriate regulations for prevention of environmental contamination by genetically modified organisms. We realize that this is not a concern covered by the FDA. But we would urge the EPA, by copy of this letter, to study the Royal Society of Canada's report. The recommendations in it relative to environmental protection are, we believe very apt.

Sincerely,

Elizabeth Harris

Elizabeth Harris
Executive Director

cc. EPA Administrator Christine Todd Whitman

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