Maine Organic Farmers and Gardeners Association

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

March 6, 2001

RE: Docket No. 00D-1598 and 00N-1396
Proposed Rule on Premarket Notice Concerning Bioengineered Foods and Draft Guidance on Labeling

Dear Commissioner:

Because the proposed rule and the draft guidance are interrelated, the Maine Organic Farmers and Gardeners Association (MOFGA) submits a common response to both. Two copies of the response are enclosed in this mailing for your convenience. MOFGA is a non-profit organization with over 3,400 members, who include farmers, gardeners, and consumers dedicated to ensuring the availability of healthful food, to sustainable rural economies and to protection of the environment. Over seven years ago, MOFGA was instrumental in proposing the first mandatory GE labeling legislation in the nation, and thereafter was represented on the Maine Commission to Study Genetic Engineering and Biotechnology, created by the Maine legislature and appointed by the governor. The Commission's charge was to examine the adequacy of federal legislation and regulation to address the various environmental and health issues presenting by the emergence of genetic engineering technologies. To that end, the Commission (on which I served) met at length with FDA coordinator of biotechnology James Maryanski and other experts, read extensively, and met and deliberated over a year and a half.

The broad-based Commission's final report issued in March, 1996, and provided to the FDA, reported a consensus identifying three inadequacies in the current system of biotech oversight: lack of federal mandatory labeling for genetically engineered foods, lack of an effective system of mandatory pre-market notification, and lack of an effective system of federal legislation to assess the risks of environmental release of genetically engineered fish.

MOFGA is pleased that the Commission has, although belatedly, responded to one of these concerns – premarket notification. MOFGA concludes, however, that the system of premarket notification is inadequate to provide the assurance the public needs about the safety of these products, and that the Commission's policy on labeling is in fact a giant step backwards.

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P. O. Box 170, Unity, Maine 04988 • **Phone:** *(207) 568-4142*
Fax: *(207) 568-4141* • **E-mail:** *mofga@mofga.org* • **Web:** *www.mofga.org*

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The Commission's logic is a bold exercise in making contradictions look like consistency. The agency "reiterates its view...that transferred genetic material can be presumed to be GRAS and "is not altering its view...that there is unlikely to be a safety question sufficient to question the presumed GRAS status..."

However, the Commission goes on for the first time to formally concede that "because [genetic engineering] can introduce genetic material from a much wider range of sources than previously possible, there is a greater likelihood that the modified food will contain substances that are significantly different from, or are present in food at a significantly higher level than, counterpart substances historically consumed in food." The Commission also concedes that allergenicity is a bigger issue with GE foods: "because genes code for proteins, and virtually all allergens are proteins...by increasing the range of potential proteins that can be introduced into food over that possible by traditional breeding, there is an increased potential for introducing an allergen into a food developed using rDNA technology." Finally, the Commission notes that the future directions of biotechnology suggest the potential for more, not fewer, of these troublesome issues: "FDA expects that with the increased introduction of multiple genes [as opposed to current single gene inserts], unintended effects may become more common."

We find these three admissions refreshingly groundbreaking in candor. However, the FDA's response to these issues -- concerns that consumer activists have been raising for years -- appears woefully inadequate. Mandatory premarket notification is clearly a step in the right direction. But "notification" is not at all the same as "regulation" or "registration," as we have with new pesticides, or pharmaceuticals. After receiving notification of a new biotech food, the Commission does not have to confirm, approve, or in anyway put its stamp of approval affirmatively on the company's decision to market the product. All it has to say is that, based on its evaluation of the premarket notice, "the agency has no questions, at this time, regarding [the manufacturer's] view that the bioengineered food is as safe as comparable food..." We feel consumers will conclude that this is appallingly flimsy assurance, for all of their tax dollars, especially given the admitted risks presented by this new technology.

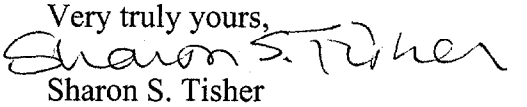
Assuredly, under this new system some diligent agency staff might uncover a problem with a proposal, and stop it before it hits the market. However, without a mandate and guidelines from either Congress or the FDA spelling out standards for a determination of safety, the safeguards provided by premarket notification are entirely a function of agency discretion and resources. Astonishingly, the guidelines for the premarket notification contain no requirement for any safety testing.

Predictably, the FDA's guidance on GE labeling leaves the consumer more, not less in the dark. Producers won't be able to put "GMO-free" on their label. Instead, they may be able to put "We do not use ingredients created through the use of biotechnology in this product," a statement that won't fit on most labels. The FDA's observation that

it's difficult to ensure "zero" presence of GE ingredients in food is, in effect, an admission of the failure of the USDA.

One most disturbing sentence suggests that *any* effort to voluntarily label that a product does not contain GE ingredients might draw FDA condemnation: "A statement that a food was not bioengineered...may be misleading if it implies that the labeled food is superior to foods that are not so labeled." One wonders whether the right hand knows what the left hand is doing. Did the individual who drafted this "guidance" read all of the admissions in the proposed premarket notification rule about the greater risks with GE technology? Clearly, a food which presents fewer, or more conventional and more fully tested risks may be rationally regarded by a reasonable consumer as "superior" to foods which present new and largely untested risks – risks which have recently been acknowledged by as esteemed an institution as the National Academy of Sciences (Genetically Modified Pest-Protected Plants: Science and Regulation, National Academy Press, 2000). When will the Commission finally understand that the consumer has a right to choose whether or not to take such risks, and that right can only be provided by mandatory labeling?

Very truly yours,



Sharon S. Tisher
Chair, Public Policy Committee

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Maine Organic Farmers and Gardeners Association
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