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Docket No. OON-1396 & Docket No. OOD-1598
FDA Commissioner
Documents Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear FDA Commissioner:

I am writing to express my deep concern over the proposed rules that FDA issued on January 18 concerning foods that contain genetically engineered (GE) ingredients. Whereas the proposed rule does require industry to provide the FDA with written notice and summary data 120 days before marketing a new GE food, it does not require either pre-market safety testing or mandatory labeling of either existing or new GE foods. Furthermore, GE food crops **already** on the market are exempt from this "pre-market biotech food notice" requirement. In other words, all US citizens will continue to serve unknowingly as guinea pigs in an uncontrolled national GE crop feeding experiment. *This violates US citizens' right to know and to choose what they eat, and it may also constitute a significant threat to public health.*

FDA's conclusion that most GE foods are "generally recognized as safe" and "essentially equivalent" to conventional, non-GE **foods** appears hasty at best, and is probably incorrect. Recent studies by toxicologists in Egypt show that ingesting foods with the Bt gene may cause cellular changes in the digestive tract that could produce symptoms of "mild food poisoning or intestinal flu." The presence of an "antibiotic resistance marker gene" in all GE food crops **currently** on the market raises a real concern that this gene could move into microbes through the process of "horizontal gene transfer" in the soil or in mammalian digestive tracts. This could contribute to the growing epidemic of antibiotic-resistant human pathogens that already thwarts doctor's efforts to treat infectious diseases. Finally, moving any gene into a "foreign" molecular environment (e.g. moving bacterial or fish genes into a food crop species) may produce unexpected allergens or toxins in the GE food. *Thus GE foods present significant potential hazards, and must undergo rigorous safety testing, similar to that required for a new pesticide.*

GE food crops also present serious environmental hazards. Crops containing the Bt gene for pest control exude large quantities of Bt toxin into the soil, where it persists for up to a year. Unlike the smaller quantities of Bt toxin added to the environment in Bt sprays, the toxin from **Bt**-engineered crops can hurt or kill any soil insect, mite, spider or centipede that comes in contact with it. Recent research has shown that these soil organisms are essential to soil fertility, and therefore to the security of our food supply. **Pollen drift from Bt crops** may also hurt non-target species of butterflies and other insects aboveground. *Concerned consumers have a right to choose foods that are produced in an Earth-friendly manner.' The FDA policy must protect this right.*

Finally, the proposed FDA **guidelines** regarding voluntary labeling of foods as either containing GE ingredients, or as being **GE-free**, places an unfair burden on those food vendors and food companies who choose to avoid all GE ingredients in their foods, and to market their food as

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GE-free. Sadly, the entire food system has become so permeated with foreign engineered genes (as a result of GE-crop pollen drift in the field, and accidental commingling at grain elevators) that a “zero tolerance” for foods labeled “GE-free” is unrealistic. This situation threatens to foreclose a vast market for GE-free foods for those farmers, food processors and retailers who want to produce and market GE-free or organic foods. Since it is the large biotech corporations who introduced these foreign genes into our agricultural environment in the first place, *it is entirely unjust that organic or GE-free food producers end up bearing the costs when accidental GE contamination occurs. The final FDA policy on labeling of GE-containing and GE-free foods must correct this injustice.*

I urge the FDA to take the following specific steps to develop and implement a GE food policy that protects citizen rights, public health farmers and the environment.

1) FDA must require pre-market safety testing of all new GE foods. Furthermore, FDA must require safety testing of all GE food crops already on the market.

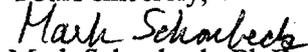
2) FDA must require a pre-market environmental review of all existing and new GE food crops, and must publish the results of this review.

3) FDA must implement mandatory labeling of all GE foods, so that US citizens can choose whether or not to be part of this nationwide feeding experiment. Furthermore, GE food labeling will facilitate diagnosis and treatment of people who suffer unexpected allergic or toxic reactions from these foods. It also protects the religious freedom of those citizens whose religious or ethical convictions oblige them to avoid certain GE foods (e.g. those with animal genes) or all GE foods. *Mandatory labeling of GE foods is an issue of basic human rights!*

4) FDA must set reasonable tolerance limits for foods to be labeled as “GE-free.” The limits must be low enough to protect consumers from potential hazards from GE-containing foods. However, this tolerance limit should not be “zero” for widely-engineered crops such as corn and soybeans – unless or until GE contamination of organic and non-GE farmland and grain crops can be cleaned up and eliminated. A tolerance level of 0.1% GE content for corn and soy marketed as GE free has been suggested by some food safety advocates.

5) Finally, FDA policy must ensure that producers and marketers of GE-free foods are protected from liability and indemnified for losses in the event that their products become GE-contaminated due to pollen drift or accidental post-harvest commingling. The only exception would be in the event that the contamination clearly resulted from negligence on the part of the GE-free food producer or marketer.

Yours sincerely,


Mark Schonbeck, Ph.D.

Crop and soil scientist; vegetable gardener, and concerned citizen

cc: Rep. Rick Boucher; Senator John Warner; Senator George Allen