



To the FDA Commissioner,
Division of Dockets Management (HFA-305),
Food and Drug Administration,
5630 Fishers Lane, Room 1061,
Rockville, MD 20852, USA
Docket ID 2004D-0369

VIA Email: fdadockets@oc.fda.gov

Dear Commissioner Crawford

We are writing to you as representatives of three civil society organisations, the EED (Evangelischen Entwicklungsdienst -- the Church Development Service) from Germany, the Institute for Agriculture and Trade Policy (IATP) from the United States, and Gene Campaign from India to urge you to withdraw the proposals contained in FDA's "Draft Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use".

The stated purpose of this Guidance is to set up a voluntary mechanism for "early food safety evaluation" of new proteins from experimental genetically engineered plants intended for food use, which are being field tested. This Guidance would address the likelihood that cross-pollination and commingling of seeds will occur, resulting in the presence of untested novel proteins in the food supply.

The proposed draft guidance is worrisome for several reasons. In an area as environmentally sensitive as this, where novel proteins, such as pharmaceutical molecules, could escape from test plots and contaminate the food chain, the guidelines proposed by the FDA are only voluntary, so a company need not undertake appropriate and adequate testing. Furthermore, the guidelines on adventitious presence have been kept so open ended that there appears to be no upper limit to the amount of contamination that would be permissible. This permissiveness would suggest that there is no rigorous regulatory

discipline to keep the food chain secure from contamination by potentially harmful molecules.

The FDA has not stated what, if any kind, of tests will have to be conducted by the crop developer to evaluate contamination from experimental fields. This lack of a monitoring exercise will ensure that early detection of contamination in the field will not be possible. Resulting contamination problems could become irreversible by the time they are detected.

Little attention has been paid to monitoring health safety as well. There are no clear provisions to test for allergenic or toxic response to novel proteins produced by GM organisms making the proposed “early food safety evaluation” fully inadequate for genuine food safety evaluation,

We propose that more comprehensive data than is required at present, be provided. All information that may affect public or environmental health may not be submitted as Confidential Business Information under the Administrative Procedures Act. The Guidance fails to mention the need for comprehensive animal feeding trials or tests for unintended effects caused by genetic engineering. Such unintended effects are acknowledged as risk factors by the Codex Alimentarius Commission, the joint agency of the World Health Organization and the UN Food and Agriculture Organization, responsible for, inter alia, risk analysis guidelines for foods derived from agricultural biotechnologies. In the absence of mandatory test protocols that are specific and rigorous, companies will in all likelihood fail to provide the necessary scientific information required in the Codex risk analysis guidelines, much less to prove safety beyond reasonable doubt.

Such a permissive regulatory system as the draft Guidance proposes threatens to jeopardise human and animal safety as well as environmental integrity from the contamination that is likely to result from experimental plots of GM plants producing novel proteins. In the wake of the StarLink and Prodigene contamination cases in the United States, this proposed Guidance appears to indicate that regulators have concluded that their highest priority is not to protect public and environmental health, but to offer crop developers the legal means to avoid liability for contamination caused by their products. We therefore urge the FDA to reflect on its proposed actions and withdraw the recommendations proposed in this Guidance.

As organisations that are closely involved with agriculture and food security in developing countries EED, Gene Campaign and IATP urge the FDA to elaborate strict rules and procedures to prevent contamination of the food supply with transgenic proteins. FDA should replace its current non-rigorous voluntary biotechnology consultation process with a mandatory, science-based and rigorous review process designed to ensure food safety. Such safety assessments should be long term and required to be conducted on the whole plant, not just on the new substance that the genetically engineered plant is designed to produce.

All countries, particularly net food importing developing countries that are likely to import food from the United States, have the right to require the FDA to introduce greater rigour in its testing procedure and its guidelines. In a globalised market with an integrated food chain, the lack of caution on the part of a major food exporting country could expose the public and environmental health of other countries to unacceptable risk. The FDA guidance as it stands would simply permit companies and developers to allow experimental genetically engineered crops to enter the food supply in the US and from there to other

countries. This regulatory permissiveness violates the rights of those nations and communities who have chosen to remain GM free .

It is unclear how the FDA, with this Guidance, intends to comply with other countries' domestic regulations for unapproved or unauthorized genetically engineered organisms. Most developing countries lack the regulatory capacity and means to adequately enforce bio safety and the reality remains that unapproved genetically engineered organisms may slip through.

We are especially concerned about FDA's reported intention to use this Guidance as an international model to address the presence of low levels of genetically engineered plant material in non-genetically engineered crop fields. This would amount to forcing other countries to accept contamination of their food supplies by genetically engineered plants and denying them the right to exercise caution in the interest of the welfare of their people and their environment. The latter has special significance for those countries that are centres of origin and diversity for the major crop plants. Risking contamination of such unique gene pools is nothing short of irresponsible since such an action could have the potential to jeopardise global food security.

Given the seriousness and far-reaching impacts of the FDA's proposals, we will continue to raise this issue with our Governments. We also pledge to work towards ensuring zero tolerance for unapproved and experimental transgenic proteins in the food supply, and for our countries to remain GE-free.

Yours sincerely,
Sd/-

Dr. Rudolf Buntzel-Cano
Church Development Service, Germany

Dr. Steve Suppan
Institute for Agriculture and Trade Policy, USA

Dr. Suman Sahai
Gene Campaign, India