



January 24, 2005

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane Rm. 1061
Rockville, MD 20852

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RE: Draft Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use; Availability

Docket No. 2004D-0369

Dear Sir or Madam:

The National Food Processors Association (NFPA) submits the following comments to the Food and Drug Administration's (FDA) notice (69 FR 68381) concerning draft guidance for early food safety assessments for new plant derived proteins.

The National Food Processors Association is the voice of the \$500 billion food processing industry on scientific and public policy issues involving food safety, food security, nutrition, technical and regulatory matters and consumer affairs. NFPA's three scientific centers and international office (Bangkok, Thailand), its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical assistance, education, communications and crisis management support for the Association's U.S. and international members. NFPA members produce processed and packaged fruit, vegetable, and grain products, meat, poultry, and seafood products, snacks, drinks and juices, or provide supplies and services to food manufacturers. In 2005, NFPA will become the Food Products Association (FPA).

NFPA supports the concept of an early food safety assessment and the timely evaluation of new protein safety information by FDA; however, we have several specific recommendations and comments regarding the guidance and the scope to ensure that these guidelines are universally followed and that they accomplish their intended objectives. We appreciate that this draft guidance is forward looking and, if followed, could contribute to preventing adulteration and unwarranted disruptions in the food supply, should an unapproved trait enter the food supply. We believe following this approach will enhance the overall regulatory effectiveness of the U.S. biotechnology coordinated framework.

Comments

- First line of defense against loss of containment

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While NFPA believes establishment of guidance is necessary, FDA should stress in a preface that the proposed policy changes are secondary to the first line of defense against the unexpected and unwanted presence of certain bioengineered crops in the food supply. First line protection starts with product stewardship and includes proper isolation measures and sufficient crop containment. We see this guidance as a back-up safeguard that must not be viewed as permission to allow relaxed isolation practices or containment efforts in field trials or during steps toward commercialization. We encourage FDA to clearly state in its guidance that it is paramount for companies to avoid materials entering the food supply by adopting aggressive and protective stewardship plans that utilize good agricultural practices and sufficient containment procedures.

- Voluntary vs. mandatory early safety assessment

NFPA believes an early safety assessment should be required (i.e. mandated) by FDA as the first step of a mandatory consultation process. With the same intended goal, and as we emphasized in prior comments to FDA, we believe that FDA should finalize its 2001 proposed regulation to require premarket notification of bioengineered foods. From our perspective, the mandatory nature of this oversight would further strengthen our domestic biotechnology policies and enhance consumer's confidence in the safety of the food supply.

It is obviously beneficial for a sponsor to begin voluntary discussion early with FDA before considerable developmental resources are expended. Upon a completed and successful early safety assessment, sponsors could then proceed with all other aspects of the consultation process. With a mandatory requirement to evaluate if the protein material is safe, we believe public confidence in the policies governing biotechnology would be enhanced. NFPA believes that given the continuing evolution of foods derived from biotechnology, it is appropriate for FDA and other agencies to exert greater regulatory oversight on new proteins entering the food supply. The food industry, the public and FDA want to be assured these new proteins are not toxic or allergenic as soon as possible.

- The stage of development when an early safety assessment is indicated

In this guidance, FDA needs to clarify at which point a developer must consult with FDA to obtain an early safety assessment. FDA should be more precise as to when is the appropriate time for this "early" evaluation to take place. We recommend FDA consider a risk-based strategy to assist companies in their decision making process. Risk would be based on the known and unknown characteristics of the plant and of the protein with health, safety and environmental risks being the primary concern. FDA could develop a matrix or a decision tree approach which would take into account known and unknown characteristics of the plants and the proteins and determine a point at which consultation with FDA regarding early safety assessment is appropriate. Other risk based considerations could include the nature of the trait, the biology of the plant, the geographic dispersion of the plantings and other specific crop issues. FDA's draft guidance should give clear and science-based direction on this issue.

- FDA's written response to a companies proposed safety assessment

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It will be essential for FDA to clearly state its conclusion about their review of the information provided by the sponsor regarding the safety of the protein and its health risk with respect to possible low-level intermittent contamination in the food/feed supply. NFPA agrees that the FDA should provide a written response upon completion of review of a submission for the early safety assessment within 120 days. We also suggest that the written response be explicit in presenting FDA's appraisal regarding that both the toxicity of the protein and the potential for becoming an allergen have been addressed in the assessment of the sponsor's information. FDA should state that they conclude that there is no potential for health or regulatory consequences (i.e. the food is not adulterated) if low-levels of this protein should enter the food/feed supply. FDA should present a conclusion, such as: there is reasonably certainty the protein would cause no harm or health impacts if consumed. Also, FDA should remind the sponsor in the guidance that if new data relative to the safety of the protein becomes available to the sponsor, that it is the sponsor's obligation to bring this information to the attention of the FDA as soon as possible.

- Aspects of food safety and scope of applications that should be examined in the early safety assessment

We agree with FDA that a sponsor should consider the new protein characteristics as to whether the new protein is an allergen or a toxin. As well as the 1992 policy guidelines for such considerations, we concur with FDA that a sponsor should also follow the protein and allergen evaluation approaches that are discussed in the Codex Alimentarius "Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants."

The FDA draft guidance document covers new non-pesticidal proteins in plant varieties intended for food use (both human food and animal feed). In the event that the new protein is a plant-incorporated pesticide (PIP), we strongly encourage the Environmental Protection Agency, under the Federal Insecticide, Fungicide, and Rodenticide Act, to also mandate a risk assessment of the new protein early in the review process.

Furthermore, we strongly encourage the U.S. Government to separately consider a policy to broaden the application of early safety assessments beyond those of new proteins in plant varieties intended for food use to include plant made pharmaceuticals (PMP) and plant made industrial compounds (PMIC) where food crops are used as the production plant. NFPA would like to work with FDA and others on the development of a mandatory early safety assessment policy for PMPs and PMICs as we recognize the consequences of an inadvertent introduction of these materials into the food chain.

Thank you for providing this opportunity to comment on the proposed guidance. If you should have any questions regarding our comments, please contact us for additional information.

Sincerely,



Jeffrey T. Barach, Ph.D.

Food Products Association (formally National Food Processors Association)