NFPA
The Food Safety People

NATIONAL FOOD PROCESSORS ASSOCIATION

March 19, 2001

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

[Docket No. OOD- 1598] Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Availability
66 Federal Register 4839, January 18, 2001.

Dear Sir or Madam:

The National Food Processors Association (NFPA) submits the following comments on the docket referenced above.

1350 I Street, NW
Suite 300
Washington, DC 20005
202-639-5900

NFPA is the voice of the $460 billion food processing industry on scientific and public policy issues involving food safety, nutrition, technical and regulatory matters and consumer affairs. NFPA's three scientific centers, its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical services, education, communications and crisis management support for the association's U.S. and international members. NFPA's 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.

NFPA commends FDA for the development of this draft guidance on voluntary label statements regarding foods that have and have not been developed with the use of biotechnology, and we urge FDA to issue final Level 1 guidance as soon as possible. NFPA also supports the substance of FDA's draft guidance. In these comments NFPA expresses its support for specific provisions of the draft guidance, and puts forward some recommendations to strengthen, clarify and reinforce the draft guidance.

WASHINGTON, DC
DUBLIN, CA
SEATTLE, WA

Reaffirmation of FDA's 1992 Policy regarding labeling of foods derived through biotechnology

NFPA strongly supports FDA's affirmation, in the background section of this draft guidance, of its position, stated in May, 1992 (57 FR 22984), that there are limited circumstances where labeling of foods derived through biotechnology would be required. NFPA concurs with FDA that the misbranding provisions of the Act lead one to conclude that there are four specific conditions in which it would be necessary to label material differences in foods, but not the processes through which those material differences were derived.

The four conditions under which such material differences must be labeled are:

- If a bioengineered food is significantly different from its traditional counterpart such that the common or usual name no longer adequately describes the new food, the name must be changed to describe the difference.

- If an issue exists for the food or a constituent of the food regarding how the food is used or consequences of its use, a statement must be made on the label to describe the issue.

- If a bioengineered food has a significantly different nutritional property, its label must reflect the difference.

- If a new food includes an allergen that consumers would not expect to be present based on the name of the food, the presence of that allergen must be disclosed on the label.

NFPA further concurs with the Agency that there is no basis for concluding that the fact that a food or its ingredients was produced using bioengineering is a material fact that must be disclosed under sections 403(a) and 201 (n) of the act. NFPA thus strongly supports FDA's reaffirmation of its decision to not require special labeling of all bioengineered foods.

NFPA agrees that the misbranding provisions of the Federal Food Drug and Cosmetic Act – Sections 403(a) and 201(n) – form the authoritative basis both for FDA's determination of those circumstances where labeling of material facts is required, and for determining whether any voluntary food label statements on biotechnology are truthful and non-misleading.

Label Claims about the Presence of Food Components Derived through Biotechnology

NFPA supports FDA's preference for the terms "biotechnology" and "genetically engineered" to describe foods from plants derived through recombinant DNA technology. NFPA recommends that these terms be used consistently in the example claims, to clarify that it is the plant sources of foods and food ingredients that are developed through biotechnology, and not the food ingredients themselves. This approach would be consistent with the care FDA has used to ensure that the terminology used to describe the technology is neutral in tone. As FDA has noted, suggestions that food products or ingredients are "bioengineered" tends to alarm some consumers with a fear of the technology. For example, FDA cites a sample biotechnology presence claim "This product contains cornmeal that was produced using biotechnology." NFPA believes this example should be worded "This product contains cornmeal from corn that was produced using biotechnology. '' Likewise, the example "These tomatoes were genetically engineered to improve texture" should be rephrased "These tomatoes are from plants that were genetically engineered to improve the texture of the fruit. ''

NFPA supports FDA's advice that voluntary terms that describe an ingredient of a multi-ingredient food as "bioengineered" should not be used in the ingredient list of the multi-ingredient food, as these terms would constitute prohibited intervening material in the ingredient list. NFPA also believes that statements that a food was genetically engineered or derived through biotechnology should not be presented as a descriptor in conjunction with a statement of identity, since such characterizing statements are not generally appropriate as part of a common or usual name. These considerations should also be applicable to statements that a food is not derived through biotechnology.

Label Claims About the Absence of Food Components Derived through Biotechnology

NFPA supports FDA's decision not to encourage the use of claims such as "GMO Free," as such claims may be inaccurate, misleading, and not well understood by consumers. NFPA further supports FDA's conclusion that terms such as "not genetically modified," "GMO free" and "free of genetically modified organisms," which include the word "modified," are not technically accurate, since conventional techniques of plant development also result in products that are "genetically modified." For clarity, any such terminology should provide a clear context that refers to bioengineering technology. Notwithstanding the fact that most foods and food ingredients are, or are derived from,

parts of organisms, NFPA also agrees with FDA's assertion that the term "GMO free" may be misleading on most foods. NFPA concurs with FDA's conclusion that the term "free" in a claim for absence of bioengineering may be inaccurate, since consumers assume that "free" of bioengineered material means that even adventitious bioengineered material would not be present. As FDA asserts there is currently insufficient scientific information to establish a threshold for use of the term "free," NFPA believes the use of that term in a voluntary biotechnology absence claim would be potentially misleading. NFPA further supports the concept, advanced by FDA, that analytical testing provides the best methods for substantiating any such absence claim with scientific data, and that methods for testing a wide range of foods are not currently available.

Reinforcing the point we expressed above regarding consistent use of terminology, NFPA believes that the illustrative example of a voluntary absence claim "We do not use ingredients that were produced using biotechnology" should be restated as "We do not use ingredients from plants that were produced using biotechnology."

NFPA supports FDA's advice that a statement that a food was not bioengineered or does not contain bioengineered ingredients may be misleading if it implies that the labeled food is superior to foods that are not so labeled. Likewise, NFPA believes that such statements would be misleading if they state or imply any type of warning regarding foods developed through biotechnology. NFPA concurs with FDA that the entire context of the label and labeling would need to be evaluated with respect to purported representations of superiority, or representations that could be characterized as warnings.

NFPA also supports FDA's decision regarding selective representations of absence of biotechnology, or statements that an ingredient was not bioengineered if there is another ingredient in the food that was bioengineered. Such representations would tend to mislead consumers. NFPA agrees with FDA that a claim may be misleading if it suggests that a food or ingredient is not bioengineered when there are no marketed bioengineered varieties of that category of foods or ingredients.

Substantiation of Label Statements

NFPA supports FDA's advice that claims that a food or its ingredients are and are not bioengineered should be substantiated. FDA's approach, as articulated in the draft guidance, suggests that the Agency believes that claims should be substantiated by a reasonable basis, recognizing that validated testing, if available, is the most reliable way to identify bioengineered foods or food ingredients, but acknowledging that documentation, including information on special handling or segregation, may be appropriate to substantiate claims.

NFPA agrees with FDA's advice that a "certified organic" statement in compliance with the recently promulgated National Organic Program standard, likely would be sufficient to substantiate a claim that a food was not produced through biotechnology, since biotechnology is a method excluded from "organic" production and handling. NFPA notes that such a "certified organic" representation should be expressed with care so as not to suggest or imply that the food is "free" of recombinant DNA. The requirements of the National Organic Program standard are based on certification of production and handling techniques, and would not address any adventitious presence of material derived through biotechnology. As absence of such material could not be assured through certification, any biotechnology "free" claim on organic food products should be substantiated through appropriate analytical testing, which is not part of the National Organic Program standard. Because of their potential to mislead consumers, biotechnology "free" claims on "organic" foods warrant special attention, and NFPA urges FDA to be vigilant for such representations.

NFPA again commends FDA for developing this draft guidance on voluntary biotechnology statements for food labels, and we urge FDA to issue final Level 1 guidance as soon as possible.

Thank you for the opportunity to comment on this important issue.

Sincerely,

Regina Hildwine
Senior Director, Food Labeling and Standards
Regulatory Affairs