Representing, Educating and Promoting the Restaurant/Hospitality Industry

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NATIONAL RESTAURANT ASSOCIATION

March 19, 2001

FDA Docket Clerk
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
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Docket No. OOD-1598: Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Availability

Dear Sir or Madam:

Founded in 1919, the National Restaurant Association is the leading business association for the restaurant industry. Representing more than 46,000 members and 235,500 restaurant outlets, we would like to comment on the agency draft for Industry on voluntary labeling indicating whether foods have or have not been developed using bioengineering, Federal Register: January 18, 2001 (Volume 66, Number 12), pages 4839-4842.

The National Restaurant Association is strongly committed to serving safe food, and is working as a partner to educate the public about important food safety messages. However, we believe that FDA should not require labeling of bioengineered ingredients or foods in their entirety, particularly on restaurant menus.

Food labels required by the FDA typically warn consumers of risks based on scientific analysis or provide certain specific nutritional information. By law, these food labels must be truthful and not misleading. If manufacturers use a labeling term the FDA considers misleading, FDA could consider the product misbranded or adulterated and request a recall or even seize the product. This standard must be upheld even as some companies wish to provide more information about bioengineered foods to those consumers who desire it.

FDA released a policy in 1992 regarding foods derived from new plant varieties which states that the agency will not regulate recombinant DNA ("rDNA" or "bioengineered") foods as a class any more stringently than conventionally produced foods. FDA maintains that use of rDNA technology is not a "material fact" with respect to labeling, rDNA foods do not differ from other foods in any meaningful or uniform way, and that they as a class do not present different or greater safety concern than traditional food varieties. FDA's policy is supported by all the available science, and consistent with existing law.

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The National Restaurant Association supports the agency's position that bioengineered foods as a class do not require special labeling. Mandatory labels based on the process by which a food is produced, rather than on the composition of the final product, could force producers and manufacturers to separate -based solely on the use of bioengineering – commodities, ingredients, and final products. This would require separate storage, transportation and processing facilities, adding costs that would be passed along to the consumer. Perhaps more importantly, if there are no changes to the nutritional content or safety of the product itself, this type of labeling will not result in any additional protection of our food supply or any additional meaningful information to the consumer.

Government labeling requirements are intended to provide consumers with significant information about a food. Mandating labeling relating to the process of food development or preparation, rather than the product itself, could inappropriately signal to a consumer that safety or nutrition has been compromised in the product, or that there is a nutritional or health benefit associated with one process over another.

Given these science-based parameters, voluntary label claims regarding the use or nonuse of bioengineering must be carefully developed so that they are not misleading. Currently, the term "organic" could be easily understood by consumers to mean the absence of bioengineered foods. Clearly, this would be the most appropriate way to accomplish consumer information demands without inappropriately stigmatizing the technology. The term "organic" provides opportunities to inform consumers without unduly restricting their choices, and gives businesses the freedom to differentiate their products in a changing marketplace.

The National Restaurant Association supports the suggestion in the guidance that in the absence of validated testing to substantiate label claims, manufacturers should document handling practices as proof that no bioengineered materials are present. The request for either testing or documentation to verify the absence of bioengineered materials for a label claim places the burden and costs of testing or record-keeping squarely on those who want to use the label and capture the market for non-bioengineered foods. We recognize that the current system may contain certain limitations for verification. This may make it difficult for documentation and this issue must be fully addressed.

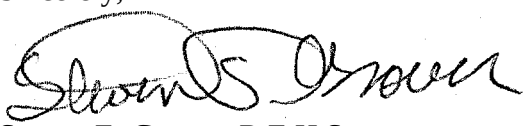
The FDA is correct that "free" or "non-bioengineered" type statements suggest zero content of the ingredient referred to on the label. If "free" does not mean zero, that is a material fact, and must be treated as a material fact when developing label statements. Furthermore, statements like "no genetically engineered materials" would be misleading on a processed product (oils, sucrose, etc.) where no genetic material or protein of any sort is present to indicate bioengineered or non-bioengineered starting materials, A clarifying statement could resolve the discrepancy, but would likely confuse consumers, because of the redefinition of commonly used terms. While clarifying statements may make a label more accurate, the additional information may be lost on consumers already saturated with the data content of food labels. Such labels with qualifying statements would be particularly unworkable on restaurant menu format.

Stating a product is "free" of a particular ingredient or contains "no bioengineered material" further implies that ingredient is unsafe or unhealthy and should be avoided. Voluntary label claims developed under this guidance are purely for marketing purposes, not to indicate health or safety. There are no significant health, safety or nutritional differences between bioengineered foods and conventional varieties; thus there is nothing to be avoided. A "free" or "non-bioengineered" claim implies a benefit where none exists. A clarifying statement would be of limited use, as it would not be an explanation, but a disclaimer. Clarifying a label claim is one thing; making it conditional by retracting it would seem confusing and contradictory.

The National Restaurant Association agrees that in the absence of a legal or scientific mandate to label bioengineered foods based solely on the use of technology, voluntary label statements are one appropriate and effective means of addressing consumers' desire for information regarding biotechnology. The National Restaurant Association supports voluntary truthful and non-misleading labeling of food products as an appropriate way for businesses to differentiate their products in the marketplace according to their own business strategies and market research.

The National Restaurant Association appreciates the opportunity to submit these comments and thanks FDA for soliciting the opinion of the restaurant industry. Please feel free to call on us with any questions you may have regarding this issue, at (202) 331-5986.

Sincerely,



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