



NFPA[®]
The Food Safety People

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

NATIONAL

FOOD

PROCESSORS

ASSOCIATION

[Docket No. 2003N-0496] Food Labeling: Health Claims; Dietary
 Guidance;
 68 Federal Register 66040, November 25, 2003

Dear Sir or Madam:

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

NFPA 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.

These comments are intended to address FDA's questions contained in the
 November 25, 2003 ANPR, and to offer responses and suggestions to the
 questions posed by the Agency. NFPA and the food industry are encouraged and
 heartened that FDA has undertaken its initiative to accommodate qualified health
 claims on the labels of conventional foods, and to clarify its views on dietary
 guidance.

NFPA has advocated for flexibility in the expression of health claims and other
 types of food label statements for nearly a decade, as evidenced by our 1994
 citizen petition to FDA on health claims and nutrient content claims policy
 (Docket No. 94P-0390), and all subsequent letters and comments on this subject

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to FDA. Obtaining flexibility for health claims was the central motivation for NFPA's 1994 citizen petition, which argued the same legal points as the *Pearson v. Shalala* decision. In the years since the *Pearson* decision, NFPA's comments and letters to FDA on health claims policy have consistently argued for applying the *Pearson* decision to health claims for conventional foods.

FDA's initiative to accommodate qualified health claims on food labels, and to clarify the use of dietary guidance, suggests that an appropriate framework should be developed to address these types of statements, so that companies may explore food label communications opportunities offered by such statements in clarity and with confidence. As we describe in the following comments, NFPA believes that qualified health claims and dietary guidance statements fit well within the existing broad statutory and regulatory framework for label statements generally, and health claims in particular, and that nominal modifications to current regulations can easily integrate principles governing both types of statements into useful rules.

Regulatory Alternatives for Qualified Health Claims

NFPA finds some degree of merit to each of the regulatory options for qualified health claims considered by FDA. Equally, NFPA believes that each option presents some problems. For example, in Option 3 -- an approach for post-market evaluation and enforcement -- FDA suggests that its enforcement authority for such an approach is not as extensive as that of the Federal Trade Commission (FTC), which has administrative subpoena power for access to a company's substantiation data for post-market enforcement of claims. Consequently, additional enforcement authority for this type of post-market enforcement is neither needed nor appropriate.

NFPA agrees with FDA that the approach it must follow for post-market enforcement of claims may be inefficient and too resource intensive to be practicable. In addition, Option 3 would not provide sufficient guidance to industry for formulating qualified health claims so that a food company could express qualified health claims with confidence. NFPA urges FDA not to pursue Option 3.

Options 1 and 2, as presented by FDA, each contain elements that could be combined for an approach that is more meaningful than the individual options contemplated by FDA. NFPA believes that there is merit to having an initial FDA review of a qualified health claim application, forming a safe harbor for a company that wishes to make such claims. It should not be necessary for FDA to pursue the Option 2 approach of developing a body of regulations on individual qualified health claims. The application or notification approach outlined in Option 1 is more reasonable and expeditious a process, which is important for communicating significant health-related information to consumers. However, the standard language and claims grading system outlined as contemplated

requirements for Option 1 present significant problems, especially regarding the presentation of qualified health claims on labels and in labeling, and may create some barriers against clear communications to consumers. Option 2 would require case-by-case rulemaking, which NFPA believes is unnecessary, but it offers potentially greater flexibility for expression of claims on labels and in labeling. NFPA believes that the ideal framework for a safe harbor for qualified health claims would combine the best features of Options 1 and 2.

Outlined below is an ideal system for a safe harbor for Qualified Health Claims. Such a system would:

1. Permit an applicant to seek specifically a qualified health claim, rather than only petition for a “significant scientific agreement” health claim;
2. Permit a petition for a “significant scientific agreement” health claim to be converted to an application for a qualified health claim if, upon FDA review and response to the petition, the significant scientific agreement standard has not been achieved. This is comparable to the current approach in FDA’s interim guidance;
3. Permit a “significant scientific agreement” health claim to be pursued concurrently, especially if a health claim petition on the same subject has been submitted by another entity;
4. Allow for evaluation under a “weight of the evidence” standard, which is then reflected in the wording of the claim;
5. Omit any reference to a letter grade or other graphic scheme on labels or in labeling to denote the degree of scientific support for claims;
6. Provide standard claim phraseology, as a safe harbor for expressing claims on labels and in labeling, and allow for optional, alternate claim language;
7. Provide for a short period of public review of the proposed claim, initiated by an FDA notice of availability in the Federal Register;
8. Be conducted in an expedited time frame, quicker than the review times established by regulation for a health claim petition;
9. Conclude with an exchange of correspondence between the applicant and FDA. The final outcome of the review, namely FDA’s letter of non-objection or objection to the claim, should be made public on FDA’s web site, and availability of the outcome should be announced in a Federal Register notice.

The use of qualified health claims can be facilitated through establishing a clear yet flexible review standard and process. NFPA suggests that the process to create a safe harbor for qualified health claims could be constructed as a new section within 21 CFR 101.70. In addition, qualified health claims can be defined in 21 CFR 101.14.

In noting that qualified health claims should be made based on a standard of "weight of the evidence," FDA clearly envisions that it should be less burdensome for industry to express a qualified health claim on a food label than to express a Subpart E health claim. NFPA agrees that a reduced burden is appropriate; however, the substantiation standard should be expressed in different terms. NFPA believes that all health claims, including qualified health claims, should be supported by "competent and reliable scientific evidence" that forms a reasonable basis for the claim as expressed, which is the claim substantiation standard adopted by the FTC. NFPA considers that "significant scientific agreement" is a high level of support through "competent and reliable scientific evidence."

The reduced burden for achieving a qualified health claim should be reflected in the time needed to achieve such a claim. NFPA supports the review time frames that FDA has articulated in its interim guidance on qualified health claims. These are reasonable time frames, and would ensure that a qualified claim could be made on labels and in labeling more rapidly than a "significant scientific agreement" claim. FDA's review of the scientific substantiation for a qualified health claim should require less time than a full review of the science needed to ensure that the "significant scientific agreement" standard is met for a health claim established under the petition process in current regulations.

NFPA commends FDA for incorporating a "reasonable person" standard for the evaluation of health claims, as articulated in the December 2002 guidance. This standard is as important as the review procedures for qualified health claims. NFPA agrees with FDA that the use of this standard will contribute to a rational legal and regulatory environment for food promotion, by making FDA's regulation of conventional food labeling consistent with the FTC's regulation of advertising.

NFPA opposes the element that FDA contemplates for Option 2, namely a letter grade or other cueing scheme to accompany a qualified health claim, to denote the degree of scientific support for the claim. The framework suggested by NFPA as a safe harbor for qualified health claims would eliminate any requirement for a letter grade or other graphic scheme on labels or in labeling. The degree of scientific support for the claim should be expressed in the wording of the claim on labels and in labeling. NFPA believes that it would be very easy for a letter grade or other graphic scheme on a label or in labeling to be misinterpreted by consumers as conveying meaning about something other than the claim, such as the quality of the food product itself. Letter grades and graphic schemes are often used on labels and in labeling, in government grading and private quality programs, specifically to communicate information about product quality. Applying a scheme that consumers may understand to have one type of meaning to a

message with another type of meaning may serve to confuse consumers about the new application. Whether or not evidence grading is used in internal FDA processes to evaluate scientific support for a proposed claim, this use should not translate to application on labels and in labeling.

NFPA believes that FDA could develop standard language, as a safe harbor, for each degree of qualified health claim, as illustrated by the interim guidance. A company could use this standard phraseology, if it preferred, or it could use alternate language of equivalent meaning.

Disclaimers, especially any negative statements, should not be required for qualified health claims. NFPA believes that the claim statement should include any clarifying or qualifying language that is essential to understanding the claim. Generally, this clarifying language would be positive in nature. Positive clarifying language would help to ensure that a qualified health claim is truthfully expressed. Such a positive statement might express that "Recent, preliminary scientific studies suggest but do not prove that a diet rich in X may reduce your risk of disease Y."

NFPA believes that excessively prescriptive health claim language and negative disclaimers would detract from the meaning of the health benefit message communicated to consumers. Mandatory negative language could promote deception by diluting the genuine meaning of the claim and the motivational effect of the claim with consumers. If a food company were required to state that little evidence supported the claim, the company likely would be discouraged from expressing the positive health message to consumers, thus thwarting the very intent of qualified health claims. NFPA believes it will be appropriate, and feasible, for FDA to decide upon standard language, as a safe harbor for qualified health claims, that is positive in tone and includes no negative disclaimers. NFPA also believes that it will be feasible and appropriate for FDA and a food company to come to agreement on similar positive language to express a qualified health claim, reflecting its scientific substantiation, without the use of any required, negative statements. The most compact claim statements that communicate clearly to consumers are likely to be the most effective.

NFPA points out that any speech restriction FDA may wish to impose on a particular qualified health claim, either through prohibiting speech or compelling speech, must be approached carefully, so that First Amendment standards are respected fully. Coerced or compelled speech requirements cannot be justified under the First Amendment except where necessary to alleviate a concrete speech-induced harm that otherwise would occur as a result of the particular iteration. A concrete speech-induced harm would mean that the expressed claim would be actually misleading to reasonable consumers without the required statement, and not just potentially misleading. NFPA believes that the burden lies with the government to demonstrate that reasonable consumers are actually misled in the absence of the required statement.

In NFPA's view, the plain words in the claim should describe the degree of scientific support for the qualified health claim. This suggests that qualified health claims should be evaluated on a case-by-case basis. As the *Pearson* decision and related court actions, and their implementation by FDA, have made clear, the articulation of health claims means choosing words that accurately reflect supporting competent and reliable scientific evidence. It is from this recognition that FDA should establish its framework for qualified health claims.

Issues Raised in the Task Force Report

1. Incentives for "significant scientific agreement" health claims. NFPA believes that FDA should abandon any approach to create a system of incentives for "significant scientific agreement" health claims. Such incentives would need to be economic in nature, and are likely beyond the ability of FDA to establish administratively. However, NFPA notes that food companies may have many reasons to decide to pursue a petition to establish a "significant scientific agreement" health claim. Food companies may wish to petition for regulatory pre-approval for a health claim that is then codified in regulations, because of the demands of their domestic or international customers, or because they want a claim authorized through a definitive decision. Petitioning for a "significant scientific agreement" health claim should remain a viable option.

2. Revised language for "significant scientific agreement" health claims. NFPA believes that FDA should consider removing the word "may" from the requirements for expression of a "significant scientific agreement" health claim. NFPA notes that the current standard language required for a "significant scientific agreement" health claim expresses that the claimed substance in the diet "may reduce risk." Reducing risk is, in itself, a qualification for the claim. Stating "may reduce risk" qualifies the health claim to two degrees. For a "significant scientific agreement" health claim, one degree of qualification, expressed as risk reduction, should suffice. Thus, stating that the substance, in the context of the diet, "reduces risk" of a disease or health related condition should be sufficient to communicate truthfully the scientific support for the "significant scientific agreement" claim. The simplest language that communicates truthfully and clearly to consumers should be permitted.

With respect to "significant scientific agreement" health claims, NFPA believes that, in an era of qualified claims, such claims should not be characterized as "unqualified." NFPA observes that all of the currently authorized health claims are qualified claims, to some degree. Every health claim, whether regulated as a 21 CFR subpart E health claim, or established under the notification procedures of the FDA Modernization Act, states that a specific type of diet emphasizing a particular substance "may" reduce risk of a particular disease. Each statement is conditional, is stated as risk reduction, and is expressed in the context of the total diet. This may be minimal qualification, but it is not

appropriate to suggest that such statements are “unqualified.” In a framework for “qualified” health claims, it is the degree of qualification that is salient.

NFPA would prefer that FDA characterize the body of health claims established by regulation in 21 CFR Subpart E and through FDAMA notifications as “significant scientific agreement” or SSA, health claims. NFPA further recommends that, if a petitioner elects, the fact of significant scientific agreement for these health claims could be expressed in the statement of the claim, as an option, to further distinguish them from other qualified health claims. Prefacing a health claim statement with a phrase such as “there is significant scientific agreement that...” or “Scientists agree that...” as an option in expression, might help consumers to understand the strength of the scientific support behind such claims. NFPA recommends, however, that this type of language should not be required for a SSA health claim.

3. Interim Final Rules for SSA health claims. NFPA believes that FDA should continue to permit SSA health claims to be effective upon proposal, as authorized under FDAMA, to the extent that they meet any of the three FDAMA conditions. The three conditions that FDAMA notes for FDA electing to make a health claim effective upon proposal are:

- (a) it would enable consumers to develop and maintain healthy dietary practices;
- (b) it would enable consumers to be informed promptly and effectively of important new knowledge regarding nutrition and health benefits of food; or
- (c) it would ensure that scientifically sound nutritional and health information is provided to consumers as soon as possible.

In theory, every SSA health claim that is put forward in a proposed rule should meet at least one of these conditions, because of the strength of the scientific support necessary for the health claim to become a proposed rule. FDA should continue to use the authority granted to it under FDAMA.

4. “FDA authorized” statements. NFPA believes that FDA should study the effects of including optional language that an SSA health claim is “FDA authorized,” and consider permitting such optional statements. FDA inquired whether there was any evidence regarding the communications effectiveness of such phrases. In January 1997, FDA made available the report of its research “Consumer Impacts of Health Claims: An Experimental Study,” which was conducted following the Keystone Dialogue on Food, Nutrition, and Health. The FDA researchers noted that, among other findings, health claims that carry organizational endorsements risk producing negative consumer reactions, compared to claims without such endorsements. This would suggest that statements such as “FDA authorized” may not enhance the credibility of health claims. However, NFPA notes that this finding is seven years old, and consumer attitudes may

have evolved. NFPA believes that it would be a useful exercise for FDA to study this question again.

5. Consumer education. NFPA believes that there is merit in FDA teaching consumers that they can have confidence in disease risk reduction statements presented on labels and in labeling. Indeed, while FDA has done a credible job in helping consumers become familiar with the Nutrition Facts label over the past decade, FDA efforts to teach consumers to have confidence in claim statements on labels have been less successful.

6. Evaluation by outside scientific groups. NFPA supports review and evaluation of the data to support health claims by third-party scientific organizations. However, because the scientific perspective needed to evaluate health claims is dietary in nature the HHS Agency for Healthcare Research and Quality (AHRQ) may not be the ideal agency to evaluate the science behind health claims for foods. NFPA believes that FDA could contract with an outside organization, or create a separate advisory body, if it wishes to institutionalize third-party health claim review. In addition, a company submitting a health claim petition or application for a qualified health claim should be able to engage a third party for review of the scientific evidence, and the summary of findings from such a review should be given significant weight in the consideration of health claims.

7. The meaning of “competent and reliable scientific evidence.” NFPA commends FDA for its deliberate study of the nature of “competent and reliable scientific evidence,” the FTC standard for substantiation of claims.

This substantiation standard would mean that the claim as expressed is supported by scientific evidence, and that the expression of the claim should take into account all available scientific evidence. A claim that reflects “competent and reliable scientific evidence” should stand on its own merits, given the plain language of the claim itself. Application of the FTC standard of “competent and reliable scientific evidence” forming a reasonable basis for the claim would ensure that claims are truthful, non-misleading, and adequately substantiated. This is, in fact, consistent with the concept of support for health claims. Significant scientific agreement can be viewed as a high level of support through “competent and reliable scientific evidence,” as a necessary level of support for health claims established by regulations or through FDAMA notifications, while lower levels of support through “competent and reliable scientific evidence” could be reflected in qualified health claims.

There is no legal or scientific basis for applying a different substantiation standard to claims appearing on a food label from claims appearing in advertising, promotions, internet, or elsewhere. There is nothing about “health claims” that sets them apart distinctively from other technically oriented product claims for which scientific evidence is required to establish a reasonable basis for the claim. As FTC policies and enforcement approaches have borne out over the years, this substantiation standard based on “competent and reliable scientific evidence” is a strong standard, and supportive of

truthful, non-misleading claims. Such a substantiation standard can accommodate mechanistic and epidemiological evidence in support of a claim. NFPA urges FDA to include such evidence in its consideration of the scientific support for qualified health claims.

NFPA does not believe that applying the FTC substantiation standard would lead to spurious claims on food labels. Food companies invest in the integrity of their food products, related not only to product safety, but also to truthful, substantiated label statements. Due diligence in developing food label statements ensures that they are truthful and substantiated. Using the same standard lets labeling and advertising exist harmoniously.

Issues for future consideration

NFPA encourages FDA to collect comments and resolve the issues related to disqualifying nutrient levels and minimum nutrient contribution requirements for health claims. Prompt resolution of these issues, which was action requested in NFPA's 1994 petition, is important to health claim policy reform, and to the First Amendment context under which qualified health claims are being considered. NFPA looks forward to the continuing dialogue on these subjects in the very near future.

Dietary Guidance

NFPA appreciates and supports FDA's pronouncements concerning the nature of dietary guidance messages that were put forward in web-based statements in July and August 2003. Because of the similarity in language between dietary guidance messages and health claims, both SSA and qualified, NFPA believes that it is necessary for FDA to draw clear distinctions between health claims and dietary guidance statements. NFPA urges FDA to recognize that dietary guidance should be about foods and categories of foods that are integral to the diet. NFPA believes that a valid dietary guidance message could use an individual food as an example of a category of foods useful in diets that promote good health, if scientific evidence supports the use of such a food as an example of the category. The use of foods as examples of categories in dietary guidance messages can be made clear in FDA preambles or similar guidance.

FDA has raised questions as to whether the FDAMA notifications on whole grains should be considered health claims or dietary guidance messages. There are now two FDAMA health claim notifications related to whole grains: the 1999 notification by General Mills, Inc., and the 2003 notification by Kraft Foods. NFPA believes that FDA's question is moot; the two statements are valid FDAMA notifications of health claims. Any action by FDA to reverse historical fact is not needed. Under the FDAMA authorities, such claims may be made until:

such time as the Secretary issues a regulation under the “significant scientific agreement” standard for health claims

- prohibiting or modifying the claim, and the regulation has become effective, or
- finding that the notification requirements have not been met, including a finding that the petitioner has not submitted all the information required, or
- a district court of the United States in an enforcement proceeding has determined that the notification requirements have not been met.

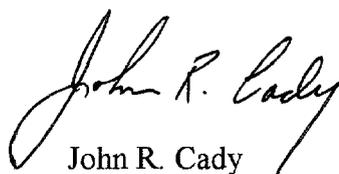
NFPA believes that it would be a needless use of FDA’s limited resources to pursue either the rulemaking or the litigation options necessary to void the whole grain health claim notifications. The dietary principles in the notifications themselves are valid, and supported by authoritative statements of scientific bodies. NFPA notes that FDA also has not suggested that the expression of the Subpart E health claim on fruits and vegetables and reduced risk of cancer (21 CFR 101.78) should be converted to dietary guidance. NFPA believes that FDA should not attempt to remedy the past by reversing this regulation and the FDAMA notifications.

NFPA believes that the most effective use of limited Agency resources will be for FDA to establish a framework for qualified health claims system that emphasizes the substantiation of the actual claim to be expressed. This approach is consistent with the implementation of policy to accommodate qualified health claims. NFPA further believes that dietary guidance statements should be differentiated clearly from health claims of all types, so that food companies may have a thorough understanding of what types of statements may require prior consideration by FDA.

NFPA looks forward to working with FDA to shape the policy for qualified health claims and dietary guidance.

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

Sincerely,



John R. Cady
President and CEO