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Directorate General Health and Consumer Protection
SANCO D4
European Commission

RE: Discussion Paper on Nutrition Claims and Functional Claims

Dear Commissioner:

The National Food Processors Association (NFPA) welcomes the opportunity to provide comments on the above referenced discussion paper and to share some recommendations towards achieving a harmonized approach to provide labeling information for nutrition claims and functional claims.

NFPA is the voice of the $460 billion U.S. food processing industry on scientific and public policy issues involving food safety, nutrition, technical and regulatory matters and consumer affairs. NFPA's three laboratory 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 over 400 member companies both in the U.S. and internationally. These companies produce processed and packaged foods, drinks and juices. Many NFPA member companies are multi-national companies, and have establishments located in the European Union (EU). Others may export products to and/or import ingredients from EU nations. Consequently, NFPA is very interested in policy development in the EU and is a strong supporter of internationally harmonized food policy. In that regard, NFPA staff has served as industry advisors to the U.S. delegation to sessions of the Codex Alimentarius for over thirty years.

NFPA Supports Harmonized EC Provisions for Claims.

NFPA commends the Commission for recognizing the importance of harmonization of rules on claims at the Community level among member countries to ensure a consistent approach and avoid confusing or misleading European consumers. In submitting comments on the White Paper on Food Safety, in April 2000, NFPA stated that, because the space on the food label is finite, labeling space should be reserved for safety, health, composition or nutrition information about the food. In that regard, NFPA welcomes EC regulations providing for the use of functional and nutrition claims and looks forward to a proposal on disease related health-claims. Truthful, non-misleading claims that can be substantiated are an appropriate

educational tool to assist consumers in making food choices to achieve a nutritionally balanced and healthy diet. NFPA is confident that European consumers, like those within the U.S., will welcome this information, and that the food industry will endorse the opportunity to inform consumers of the nutrition and health benefits of their products.

In addition, such an opportunity encourages technological innovation to develop healthier and more nutritious food products. In 1993, the U.S. FDA issued final rules to authorize eight specific health claims for food products. In the preamble to that rule, the FDA pointed out the importance of health claims to promote a healthy diet:

> **Language from the Federal Register, 58 FR 2478, January 6, 1993**
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> "Congress enacted the health claims provisions of the 1990 amendments to help U.S. consumers maintain healthy dietary practices and to protect these consumers from unfounded health claims. The House Report of June 13, 1990, states, "Health claims supported by a significant scientific agreement can reinforce the Surgeon General's recommendations and help Americans to maintain a balanced and healthful diet." Senator Orrin Hatch, one of the primary authors of the 1990 amendments, noted that diet has been implicated as a factor in the three leading causes of death (heart disease, cancer, and stroke). In addition, the statement of the House Floor Managers noted that "There is a great potential for defrauding consumers if food is sold that contains inaccurate or unsupportable health claims." The House Report characterized the need for regulation as "compelling."

The Commission, within the discussion paper, has requested comments on three specific issues: 1) definitions; 2) conditions under which claims may be made, and 3) type of evaluation and authorization system for claims. NFPA comments respond to those specific questions.

Definitions

NFPA agrees that the Codex Alimentarius definition in the General Guidelines (CAL/GL 1-1979 (Rev. 1-1991), which broadly defines claims is an appropriate starting point for a definition of "claim." However, it may also be useful to provide additional definitions for those specific types of claims that are the subject of the discussion paper. In 21 CFR 101.13, the U.S. Food and Drug Administration defines a nutrient content claim as: "A claim on a food product that directly or by implication characterizes the level of a nutrient in the food." The Canadian Food Inspection Agency uses this definition: "A nutrient content claim is any statement or expression which describes, directly or indirectly, the level of a nutrient(s) in a food

or group of foods." Additionally, the definitions in the Codex Alimentarius Guidelines for Use of Nutrition Claims (CACI/GL 23/1997) should be taken into consideration.

The U.S. and Canadian definitions clarify that a claim may be expressed or implied through graphics, illustrations, or comparisons. In some cases, failure to disclose pertinent information may be interpreted as an implied claim.. NFPA recommends that the Commission take a similar approach and assure that final regulations clarify the appropriate role of visual representations within the regulation.

A definition for a functional claim is appropriate to support international understanding of the regulation. This is particularly important because of the international confusion over the various types of health-related claims and different terminology used to describes those claims including: structure-function claims, functional claims, disease-reduction claims, and diet-related claims. In (37) of the discussion document, and within the White Paper on Food Safety, the EC has offered an appropriate definition of functional claims, "relating to the beneficial effects of a nutrient on certain normal bodily functions." NFPA points out, however, that a functional claim can also relate to a food component not recognized as a traditional nutrient (e.g. plant sterol esters with respect to cardiovascular function.) NFPA also suggests that it may be appropriate to include a definition of disease reduction claims, even recognizing that this proposal will not provide for such claims.

Conditions Under Which Claims May be Used

NFPA supports the broad use of nutrient content claims when specific criteria have been established that will govern their appropriate use and prevent misleading information. Consistency in terminology and use is critical. NFPA believes that provisions to use nutrient content claims should be applicable to all food categories, and that is also appropriate to identify the preferred language for statements and criteria for making those statements. Other nations have established criteria for a reference amount of a food that can form the basis of a claim, and separate provisions to accommodate infant foods or special populations. Some identify other rules for special nutritionals or foods for other dietary uses.

In the interest of harmonization, and to minimize duplicative effort, NFPA encourages the EC to review claims and compositional criteria that have been established within Codex and by the U.S. FDA, claims which have been authorized, and those that are now considered for revision by CFIA. Harmonization on a global basis, where possible, will strengthen consumers' understanding of the meaning and implication of labeling terms and will be beneficial to consumers and to the food industry.

Pertaining to nutrient content claims, NFPA recommends that:

1. Nutrient claims should be available for all food groups under pre-established criteria;
2. Full nutrition labeling should be mandated when claims are made to support nutrient content claims..
3. Type size and label placement should be established within general parameters;
4. Meaningless, regional or confusing terms should be avoided;
5. General conditions should be established for comparative claims, such as the identification of the reference food;
6. Provisions for the appropriate use of synonyms must be addressed;
7. Claims for food combinations should be addressed

NFPA concurs that negative claims that state foods are "free from.." or "without added…" can be misleading when these conditions are normally indigenous to a product. Only foods that have been specifically reformulated or altered to meet those requirements should be permitted to use such terms.

NFPA does believe that it is helpful for consumers to know when a food is naturally low, naturally free, or naturally high in specific nutrients and recommends that language be established to provide for this type of truthful and informative statement.

Specifically related to the "conditions" or criteria suggested for specific claims, NFPA encourages recognizing scientific data used by other nations to justify claims and points out that some claims have already been recognized by Codex Alimentarius and criteria established. Some of the member states have standards that are more restrictive than Codex and could be challenged if not harmonized or scientifically justified.

Finally, it is important that the EC establish a clear compliance policy to ensure uniform enforcement throughout the member states. Such a policy should addresses acceptable tolerance levels and provide for the use of nutrient databases that may be maintained by public or private sector entities.

Functional Claims

NFPA agrees that functional claims should be stated in the context of the total diet and should not inappropriately encourage the consumption of one specific food product. It is important to recognize that there are no "good" or "bad" foods per se. NFPA also agrees that to justify a functional claim, the food must be a significant source of the nutrient or food component in question, and those baseline quantities must be established and maintained throughout the established shelf-life of the food.

The U.S. FDA provides for the relationship between the nutrients and the "function" allowing more flexibility in labeling statements related to that relationship when specified conditions are met. NFPA believes that some flexibility is helpful to allow for abbreviated claims or to allow for more information that may be useful to the consumers. For example, the U.S. would allow additional information to state "Adequate calcium is important but daily intakes about 2, 000 mg are not likely to provide additional benefits."

Evaluation of Claims

Many nations have recognized the benefits of providing for the use of health-related claims on food labels and several nations have already reviewed substantial scientific data to support such claims. For example, the U.S. FDA has already authorized 14 health claims; Canada is proposing to allow for five diet- related claims and specific health claims are also being reviewed in Australia and New Zealand and other nations.

NFPA would, therefore, strongly encourage the EC to recognize the scientific assessments and evaluations already completed in the area of health-related claims in other nations and to draw on that information to propose labeling statements and criteria in the EC that are generally consistent with other nations. Thus, NFPA would support the establishment of a preliminary EC list on that basis. The claims on the preliminary list should not require any further petition or authorization process. Some such internationally recognized claims would relate to the following relationships:

- Folic Acid and neural tube health;
- Sugars and dental caries;
- Calcium, Vitamin D and bone density;
- Sodium and blood pressure;
- Fat, saturated fat and cholesterol and cardiovascular function;
- Fiber and bowel function;
- Fiber and cardiovascular function;
- Soy Protein and cardiovascular function;
- Potassium and blood pressure;
- Plant and sterol esters and cardiovascular function.

The establishment of a transparent review and authorization process to provide for additional claims as scientific data becomes available would also be appropriate. However, the suggested "two-step" Swedish system that would require an application and approval of the relationship and, then, a pre-approval for a specific

product to use that claim would be resource intensive and unnecessary when criteria for the use of the claim could be established in general terms. Also, a system of notification to member states, which would then validate a claim for the entire community, seems inappropriate. That approach would be inconsistent with the general EC objective, establishment of a single European Food Authority as the single scientific authority for the community. In addition, that approach would not provide consistency in the evaluation process or equal opportunity for members of the Community and the global community to comment. It may also result in the simultaneous consideration of similar applications by several states resulting in an unnecessary duplication of data collection and documentation process.

NFPA appreciates your consideration of these brief comments and welcomes an opportunity to provide more detailed comments upon release of the draft regulation.

Sincerely,

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