

CCNFSDU, Bonn, 3-7 November 2003

## **Draft Recommendations on the Scientific Basis of Health Claims (at Step 3)**

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The Council for Responsible Nutrition (CRN) believes that a CCNFSDU position on this topic is pivotal to further work in the area of nutrition claims and health claims in Codex. The specific language about “health claims” in the draft position paper (CX/NFSDU, 03/9) require further editing to avoid misdirecting the attention of this committee to issues under other authorities, and to avoid misrepresenting the scientific evidence in this area. CRN’s comments are offered to help solve those problems.

### **1. Preamble**

We agree that no food should be described or presented in a manner that is false, misleading or deceptive. However, the impression created in this draft is that the labeling language in a health claim may not be scientifically based, and thus subject to varying interpretations. This impression is false and needs to be removed. Therefore, the remainder of the sentence, “...or is likely to create an erroneous impression regarding its character in any respect,” should be deleted.

The second bullet, “Health claims should be forbidden if they cannot be justified,” also should be deleted—the sentence preceding it says that statements cannot be false, misleading or deceptive- in fact they already would not be acceptable.

The need to be consistent with “national nutrition policy and support that policy,” also should be deleted—this document is intended to be recommendations for the scientific basis. How and when the statements are used are the subjects for a different document.

Statements should describe what the provisions are intended to do rather than what they are not intended to do. Delete the sentence, “They are not intended for the evaluation of the safety and the quality of the products...” Safety and quality of products are separate issues that are different from the issue of validity of claims

### **2. Nature of the evidence provided on the characteristics of the product, on which the claim is based**

#### **2.1 Identification and stability of the food**

- Bullet one—the requirements for information should appropriately be those already existing in Codex texts for specific foods: these foods and ingredients would need to meet Codex standards and/or specifications.
- Bullet two—whatever are the shelf life requirements for other areas of the Codex standards would be required here- this statement adds nothing new to that requirement and should be deleted.

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- Bullets 3 and 4—validated analytical methods used would be subject of language within CCMAS, as would appropriate sampling and activity. Statements on the label would have to be verified and would be subject to scrutiny—either the statement on the label is correct or it is not. How that is demonstrated is not the subject of this standard, and should be addressed elsewhere in Codex.

## 2.2 Safety of the product

- Bullet one- safety should be assured through other Codex standards- national legislation should not be mentioned as part of this document (delete, “or existing national legislation.”)
  - Sub-bullet one—Delete this sub-bullet. If the food safety risk assessment were required, the elements of that assessment would be part of that standard document and would not need to be included here. The safety of the ingredient or food, that is the subject of the claim, should be assured according to an appropriate risk assessment (include reference if appropriate). Interactions among food substances or constituents would be part of that risk assessment. Appropriate safety requirements should apply and be enforce for all food products, regardless of the presence or absence of claims on the product.
  - Sub-bullet two—Delete this sub-bullet. Upper levels also would be addressed as part of the food safety assessment- this document is supposed to be about the claim. Once the safety of the food or ingredient is known, it may be “assumed” the purposes of this claims document.

Nutritional safety is not part of this document; the subject is to be scientific basis of health claims. Nutritional safety should be assumed or documented; no further discussion should be required here and this section should be deleted. If safety needs to be underscored, some language could be added to the preamble; nutritional safety issues should be the subjects of a separate document that should be referenced.

## **3. Scientific requirements about the claim effect**

3.1 General requirements- it may be possible to use data and study outcomes that exist in the scientific literature rather than requiring primary data developed specifically for individual claims. The general requirement would be that the claim must be supported by appropriate scientific information. Scientific evidence would vary according to the type of claim and the claimed effect.

3.2 Nature of the scientific evidence on the claimed effect- it is unclear what is meant by the statement, “supported by scientific evidence along one or several of the following approaches.” The types of studies required for various claims should be articulated and justified based on the relative risk and the benefit established. These claims, whether in the context of the total diet, the complete food, or the effect of the constituent or substance should be justified based on the data required.

The use of epidemiological data is appropriate, and the data should be relevant to the population targeted by the claim. General agreement within the scientific community also can be used as evidence, when the scientific basis is documented.

Demonstration of the mechanism of action for a health claim should not be required. Documentation of the effect, that is, the claimed health outcome, should be supported with appropriate and sufficient scientific evidence.

Design of the studies to show effect need to be in the context of acquiring the appropriate data to support the claim. Therefore, nutritional effect studies conducted under appropriate schemes and over appropriate time spans, should be the basis of scientific evidence collected for the purpose of making a health claim.

Data to support toxicological evaluation should not be the subject of this text; it is part of the safety evaluation. Delete references to safety assessment in this text.

- 3.3. Relevance of the evidence at the population level: if the claim is made on a specific product for an identified, targeted, consumer, and the population level should not be a factor in making the claim. The claim would be more specific than population level.

#### **4. Evaluation of the scientific proofs, used to justify a claim**

We strongly support the appropriate evaluation of the scientific evidence provided.

#### **5. Periodic re-evaluation**

- Bullet one—No scientific rationale exists to require further study, either fundamental or clinical, to “resupport” a claim that has been scientifically justified. To the extent that new data arise or are developed, a claim may need to be appropriately amended. However, periodic re-evaluation of the claim may not always be appropriate, feasible, and a good use of resources.
- Bullet two—Monitoring of consumption of products in the marketplace is part of the marketing that companies do as part of their brand management. Post-marketing assessments and/or monitoring are not appropriate tools to use in this case because no “outcome” is identified for the purposes of tracking. Tracking might be appropriate if a risk has been identified and/or a specific health benefit might be accruing to the population. However, such studies are not essential for foods generally in the food supply.
- Bullet three—Expected effects, because the foods are part of a mixed and varied diet, and are not the sole source of the constituent, substance or nutrient/ingredient in the diet, could not be associated with one food. Further, adverse effects of foods would not be anticipated or the foods would not be marketed to the general population. This statement should be deleted.

We are closely following the work of the Codex Committee on Food Labeling (as provided in Appendix 2 to this document) and will continue to provide comment and input to the work product developed in that Codex Committee. Therefore, we will not provide comment on that document in this submission.

We appreciate the opportunity to provide this perspective on the text offered. The language in this document addressing the scientific basis of health claims and development of the scientific basis for them is an appropriate consideration.

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Safety considerations should apply to all foods, regardless of claims, and thus the safety discussion in the context of claims should be deleted from this draft on the scientific principles for health claims.