

**Trans-Atlantic Business Dialogue**  
**Dietary Supplement Expert Group**

**CLAIMS FOR FOOD AND DIETARY SUPPLEMENTS**

The TABD dietary supplement working group has extensively discussed the issue of claims, at various meetings in 2000 and 2001. A draft position statement was considered at a meeting in March 2001 and later modified and reconsidered at a meeting on July 17, 2001. Minor editorial amendments were agreed upon in e-mail communications in September 2001. Below is the position statement that was considered and revised by the TABD CEOs in March 2002.

This position is intended to:

- Define permissible claims.
- Realize that current discussion is limited primarily to recognize nutrients, but to use language that can broadly apply to other substances with nutrition or health benefits.
- Distinguish, within the category of claims, between nutrient content claims, comparative claims, function claims and risk reduction claims.
- Avoid drawing a distinction between nutrition function claims and enhanced function claims, on the grounds that it is difficult or impossible to support a logical distinction. The Codex efforts to distinguish between these two classes of functional claims are encountering difficulty, with good reason.
- Allow flexibility for new and innovative claims, without specifically tying that flexibility to the “novel foods” concept as defined in Europe.
- Recognize the need to provide incentives for innovative or proprietary claims, but address this issue in the sections on substantiation and general considerations, rather than in the section on definitions.

**I. DEFINITIONS**

**CLAIM** -- Any representation that states, suggests, or implies that a product has particular nutritional properties, including but not limited to the energy value and the content of protein, fat and carbohydrates, as well as the content of vitamins and minerals. Also, any claim that establishes a relation between a food or constituent of that food and health status.

- A. Content claim** -- Claim that describes the level of a substance contained in a food (“contains x amount of y,” “source of,” “high in,” “low in”).

**Examples of content claims:**

- Product x is high in folic acid
- Product y is low in sodium

- Product z contains omega-3 fatty acids
- Product a contains phytosterols
- Produce b is a good source of soluble fiber
- Product c provides “x” milligrams of beta-glucans

**B. Comparative claim** -- Claim that compares the levels of a substance or a functional activity (such as providing energy) in two or more foods (“reduced,” “less than,” “fewer,” “increased,” “more than”).

**Examples of comparative claims:**

- Product a has three times the antioxidant activity of product b.
- This chewable tablet contains x% more calcium than brand y.

**C. Function claim:** Claim concerning specific beneficial effects of the consumption of foods and their constituents on physiological or psychological functions or biological activities. (This category includes statements currently discussed in other contexts as “nutrition function” claims and “enhanced function” claims.)

**Examples of function claims:**

- Calcium helps build strong bones.
- Vitamin A is important for vision.
- Plant sterols can help lower cholesterol.
- Lutein plays a role in eyesight.
- Product x helps enhance the body’s natural defenses.
- Product y contributes to alertness and mental function.
- Contains folic acid, which contributes to the normal growth of the fetus.
- Folic acid contributes to the development of the spinal cord in the developing fetus and is therefore critical for the health of the baby.
- Iron is an essential factor in red blood cell formation.
- Vitamin C helps to enhance the body’s natural defense system.
- B vitamins are important in the function of neural tissues and therefore help the brain to stay sharp and alert.
- Vitamin D promotes the absorption of calcium and thus helps to build bone mass and increase bone strength.

**D. Risk reduction claim** -- Claim for reduction of disease risk related to the consumption of a food or food constituent, and where appropriate in the context

**Unanimously approved, March 2002**

of the total diet, that is likely to reduce the risk of a specific disease or health-related condition.

**Examples of risk reduction claims:**

- Folate may reduce the risk of having a child with a neural tube defect (NTD).
- Sufficient calcium intake may help reduce the risk of osteoporosis.
- Vitamin C may reduce the risk of colds.
- Adequate iron intake reduces the risk of anemia.
- Adequate lutein intake may reduce the risk of AMD (age-related macular degeneration).

**II. SUBSTANTIATION OF CLAIMS**

**A. Content and comparative claims** -- Substantiation for content and comparative claims should be based on assays of the finished products or other verification of product content.

**B. Function claims and risk reduction claims**

**1. Established or accepted relationships.** Function claims or risk reduction claims that reflect well established relationships may be based on the scientific literature available in the public domain and credible findings appearing in officially accepted textbooks and literature, or may reflect accepted public policy. Examples might include “calcium builds strong bones” or “adequate iron intake reduces the risk of anemia.” Such claims may also be based on authoritative statements of recognized scientific bodies, such as the National Institutes of Health (including the National Cancer Institute and the Centers for Disease Control and Prevention), the National Academy of Sciences, the American Heart Association, the European Heart Association, or the EC Scientific Committee on Foods.

**2. New, product-specific, or innovative relationships.** Function claims or risk reduction claims may relate to new, product-specific, or innovative relationships. Such claims may be based on scientific data including proprietary research or publicly available research, with the strength of the claim being related to the weight of the evidence supporting it. The following types of data may be considered:

a. **Human intervention studies** conducted in a scientifically acceptable manner and meeting the requirements of ethical committees aimed at the demonstration of relevant, significant and positive functional effects and/or positive changes in relevant health parameters.

b. **Observational or epidemiological studies** correlating intake of the substance with the claimed health benefit.

c. **Experimental studies** (in vitro studies, animal studies) as well as any other data that support the relationship between the substance and the claimed health effect.

### **III. GENERAL CONSIDERATIONS**

- All statements made in product labeling must be truthful and not misleading.
- Research should be conducted in a scientifically acceptable manner, on an adequate and representative sample of the population, over an appropriate period of time.
- The quantity of the relevant substance in the product should be sufficient to make a significant contribution to the claimed effect, and the substance should be in a form that is bio-available.
- Research should be peer reviewed and published or should be submitted to the authoritative agency along with sufficient documentation to permit full evaluation.
- Encourage research by creating incentives including but not limited to permitting exclusive claims based on proprietary data.
- Verification and scientific acceptance of appropriate markers is an important aspect of research on health-related claims, especially with regard to risk reduction claims. These may include markers of exposure (or bioavailability), markers of function (such as changes in blood levels of a risk factor), or biological endpoints (such as bone density).
- At present, notification or approval procedures vary among national authorities. Internationally consistent notification and acceptance procedures for claims would be the preferred regulatory mechanism, and could be achieved by mutual recognition of participating national authorities.

TABD Working Group on Claims and Labeling,  
Position Statement adopted by CEOs, March 2002