

Authorized Label Claims for Food Products

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Introduction

Consumers rely on food labeling for detailed information about the origin, safe handling, proper storage, and ingredient contents of a product (Figure 1).



Figure 1. Example of the use of “low sodium” nutrient content claim on a product label.

Additional labeling claims may be added to highlight a product’s attributes for marketing purposes. Allowable label claims are defined by the U.S. Food and Drug Administration (FDA) for use under predetermined conditions.

What Types of Label Claims Exist?

FDA regulations define three categories of label claims for food products: health claims, nutrient content claims, and structure/function claims.

Health Claims

Health claims are statements which connect the food product to a reduced risk of disease or health-related condition. Health claims are defined by the FDA for

use in specific conditions backed by scientific evidence. Additional instructions for allowable use depend on the nature of the claim, which can be divided into two categories: authorized health claims and qualified health claims.

▪ Authorized Health Claims

Authorized health claims have been reviewed by qualified experts with significant scientific agreement (SSA) stating the nutrient-disease relationship is well-established. SSA is a standard involving FDA review of products to ensure label claims are truthful, complete, and easy for consumers to understand; for example, “Oatmeal can help reduce cholesterol” (Figure 2).



Figure 2. Example of the use of an authorized health claim.

▪ Qualified Health Claims

Qualified health claims are established based on scientific evidence but are not supported by the SSA standard of authorized health claims. A disclaimer must follow these claims to disclose the level of supporting scientific evidence to consumers. For example, an appropriate use of this type of claim would include “eating yogurt regularly may reduce the risk of Type 2 Diabetes” on a yogurt product.

The word “may” informs consumers that evidence suggests risk reduction but is not definite. An additional following disclaimer is required, such as: “The FDA has concluded that there is limited scientific evidence for this claim.”

Nutrient Content Claims

Nutrient content claims characterize the level of nutrients in a food or compare nutrient levels to that of another food. Eleven basic terms are approved for use as nutrient content claims with guidelines established for established nutrient levels. Terms include *extra lean*, *fewer*, *free*, *good source*, *high*, *lean*, *less*, *light*, *low*, *more*, and *reduced* (Figure 3). An example of an appropriate use of this type of claim could be the use of “sugar-free” for a product containing less than 0.5 grams of sugar.

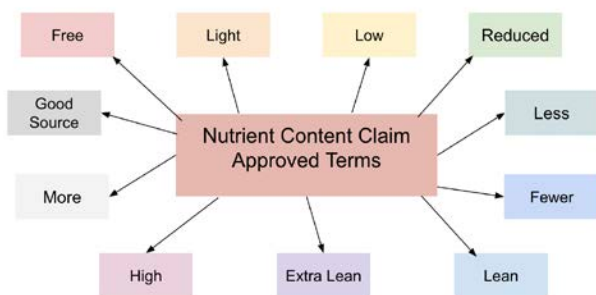


Figure 3. Eleven approved terms for nutrient content claims.

Structure/Function Claims

Structure/Function claims are applicable to foods which help maintain normal human bodily structures or functions. Approved claims fall into one of two categories: general well-being and nutrient deficiency disease claims.

▪ General Well-being Claims

These claims describe the role of a nutrient or ingredient in promoting general well-being from consumption; for example, “fiber maintains bowel regularity”.

▪ Nutrient Deficiency Disease Claims

These claims address a nutrient or ingredient’s benefit related to a classical nutrient deficiency disease; for example, “calcium builds strong bones”.

Allowable Claims for Food

Producers can find detailed requirements for health, nutrient content, and structure/function claims in

Title 21 of the Code of Federal Regulations. The following are general guidelines applicable to each claim category.

Health Claims

- Must contain ingredient or nutrient and a disease- or health-related condition
- Limited to disease risk reduction claims
- Reviewed by FDA prior to use

Nutrient Content Claims

- Must describe the nutritional properties including, but not limited to, energy value and content of carbohydrates, fat, protein, vitamins, and/or minerals
- May require a disclosure statement to appear in parenthesis after claim if product suggests health benefits from consumption but also contains other nutrients negatively impacting health.
 - Ex. “High in dietary fiber (contains 5g total fat per serving)”
- Additional information found in Section 3 of the Codex Guidelines on Nutrition Labeling

Structure/Function Claims

- May refer to signs or symptoms of natural bodily states if common and not causing significant harm (for example, constipation)

Unallowable Claims for Food

Claims not adhering to the examples and regulations described above may be considered “unauthorized claims” (for health claims) or otherwise “not permissible” for nutrient content and/or structure/function claims. Some examples of these restrictions are included below for each of the three main types of claims.

Health Claims

- May not refer to the diagnosis, cure, mitigation, or treatment of a disease (for example, “fiber prevents colon cancer”)

Nutrient Content Claims

- Claims which are not listed in the FDA-issued Food Labeling Guide are not permissible (for example, “guaranteed weight loss”)

Structure/Function Claims

- May not refer to characteristic symptoms of a disease (for example, relieves joint pain)
- May not suggest product has an effect on a specific disease

Product Labeling Support at Virginia Tech

Additional questions related to the use of claims with food products should be directed to Melissa Wright, Director of the Food Producer Technical Assistance Network (FPTAN), at foodbiz@vt.edu. The FPTAN provides labeling support for food producers making products for sale. An evaluation request form is available through program website: https://vce.az1.qualtrics.com/jfe/form/SV_eUKzGA EQg0W7i9n

A detailed description of the product recipe should be filled out on the form. Producers must list the ingredient name, amount used, description, and brand name for each ingredient in their formulation (Figure 4).

Ingredient	Amount	Unit	Description	Brand
Tomatoes, diced	500	grams	canned with salt	Contadina

Figure 4. Excerpt of product evaluation request form ingredient description.

Submitting the evaluation request form is free of charge and a producer is under no obligation to use the testing service provided by the FPTAN laboratory just by submitting a request. If a producer decides to submit samples for evaluation, the cost of services will be invoiced after services have been rendered (Table 1).

Table 1. Type and current cost of services offered through the Food Producer Technical Assistance Network.

Service	Cost (\$)
Product Evaluation, Process Validation, and Scheduled Process Report for Acidified Foods	\$125/first product \$75/each additional product
Product Evaluation and Report (includes pH and water activity analysis; no scheduled process issued)	\$75/product
Nutrition Facts Label Calculation	\$75/product
Label review, ingredient statement assistance and/or other services outside of laboratory evaluation	\$61/hour to the nearest half hour

References

- Codex Alimentarius Commission. (2009). *Codex guidelines on nutrition labeling (CAC/GL 2-1985, Rev. 1-2009)*. Food and Agriculture Organization of the United Nations. <https://www.fao.org/4/y2770e/y2770e06.htm>
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- U.S. Food and Drug Administration. *Questions and answers on health claims and food labeling*. U.S. Department of Health and Human Services. <https://www.fda.gov/food/nutrition-food-labeling-and-critical-foods/questions-and-answers-health-claims-food-labeling>
- U.S. Government. *Title 21 of the Code of Federal Regulations*. Electronic Code of Federal Regulations. <https://www.ecfr.gov/current/title-21>

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