

2013-01-23 proposal to update Health-related claims in facet P.

- QUALIFIED HEALTH CLAIM

BT: HEALTH-RELATED CLAIM OR USE [P0124]

AI: In the United States, these claims, usually referred to as "qualified health claims", are regulated by the Food and Drug Administration in the public interest, see 21 Code of Federal Regulations § 101.14

[<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=101.14>]

- STRUCTURE/FUNCTION CLAIM

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AI: Structure/function claims describe the role of a nutrient or dietary ingredient intended to affect normal structure or function in humans, for example, "calcium builds strong bones". In addition, they may characterize the means by which a nutrient or dietary ingredient acts to maintain such structure or function, for example, "fiber maintains bowel regularity," or "antioxidants maintain cell integrity," or they may describe general well-being from consumption of a nutrient or dietary ingredient.

[<http://www.fda.gov/Food/LabelingNutrition/LabelClaims/StructureFunctionClaims/default.htm>]

Syn: nutrient function claim (Codex Alimentarius); article 13 health claims (European Commission)

- HEALTH-RELATED CLAIM OR USE [P0124]

AI: Health claim means any claim made on the label or in labeling of a food, including a dietary supplement, that expressly or by implication, including "third party" references, written statements (e.g., a brand name including a term such as "heart"), symbols (e.g., a heart symbol), or vignettes, characterizes the relationship of any substance to a disease or health-related condition. See also 21 CFR 101.14

[<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=101.14>].

A claim is a health claim if in the naming of the substance or category of substances, there is a description or indication of a functionality or an implied effect on health; examples: "contains antioxidants" (the function is an antioxidant effect); "contains probiotics/prebiotics" (the reference to probiotic/prebiotic implies a health benefit). Equally, claims which refer to an indication of a functionality in the description of a nutrient or a substance (for instance as an adjective to the substance) should also be classified as a health claim; examples: "with prebiotic fibres" or "contains prebiotic fibres".

In Europe, a health claim is any statement about a relationship between food and health [http://ec.europa.eu/food/food/labellingnutrition/claims/health_claims_en.htm], and only authorized health claims are legal [see http://ec.europa.eu/food/food/labellingnutrition/claims/community_register/health_claims_en.htm].

COMMISSION REGULATION (EU) No 432/2012 of 16 May 2012 establishes a list of permitted health claims made on foods, other than those referring to the reduction of

disease risk and to children's development and health [<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:136:0001:0040:en:PDF>]