PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS

Washington
1536 16th St. N.W.
Washington, DC 20036
202-483-PETA

Los Angeles
2154 W. Sunset Blvd.
Los Angeles, CA 90026
323-644-PETA

Norfolk
501 Front St.
Norfolk, VA 23510
757-622-PETA

Info@peta.org
PETA.org

Regulations on Human Health Claims for Foods

Below are the relevant regulations regarding human health claims for foods in the European Union (EU), the United States (US), and Canada.

The EU

The European Food Safety Authority (EFSA) has several categories of health claims. General function claims "refer to the role of a nutrient or substance in growth, development and body functions; psychological and behavioural functions; slimming and weight control, satiety or reduction of available energy from the diet."[1] New function claims are "based on newly developed scientific evidence" for which "protection of proprietary data can be requested."[2] There are also claims that "refer to the reduction of disease risk or to children's development or health."[3]

For claims other than those based on the essentiality of nutrients, EFSA 's requirements of scientific evidence are as follows:

> In assessing each specific food/health relationship which forms the basis of a claim, the NDA Panel [the Panel on Dietetic Products, Nutrition and Allergies] makes a scientific judgement on the extent to which a cause and effect is established between the consumption of the food/constituent and the claimed effect (i.e. *for the target group under the proposed conditions of use*) by considering the strength, consistency, specificity, dose–response, biological plausibility of the relationship and by weighing the totality of the evidence. A grade is not assigned to the evidence.
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> *Pertinent human (intervention and observational) studies are central for health claim substantiation.* Pertinent human intervention studies are at the top of the hierarchy that informs decisions on substantiation because it is of utmost importance to show that the food/constituent can exert the claimed effect in humans and that the effect is specific for the food/constituent, an information which *can only be obtained*

[1]EFSA. (n.d.). "General function" health claims under Article 13. https://www.efsa.europa.eu/en/topics/topic/article13
[2]EFSA. (n.d.). Health claims. https://www.efsa.europa.eu/en/topics/topic/health-claims (See FAQ: What are EFSA's tasks under the Regulation?)
[3]EFSA. (n.d.). Claims on disease risk reduction and child development or health under Article 14. https://www.efsa.europa.eu/en/topics/topic/article14

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> *from human intervention studies* (EFSA NDA Panel, 2011b). Human intervention (and observational) studies can also provide evidence for a dose–response relationship and for consistency of the effect (or the association) across studies. Efficacy studies in animals and non-efficacy studies in humans, animals and/or in vitro (e.g. evidence for a mechanism by which a food could exert the claimed effect) may be part of the totality of the evidence only if pertinent human studies showing an effect of the food/constituent are available [*emphasis added*].[4]

EFSA does not require animal tests or accept animal data as stand-alone evidence for establishing health claims for foods.

The US

The US Food and Drug Administration (FDA) defines health claims as "statements about substance/disease relationships" and defines the term "substance" as "a specific food or food component."[5] It continues, "Authorized health claims in food labeling are claims that have been reviewed by FDA and are allowed on food products or dietary supplements to show that a food or food component may reduce the risk of a disease or a health-related condition. Such claims are supported by scientific evidence and may be used on conventional foods and on dietary supplements to characterize a relationship between a substance (a specific food component or a specific food) and a disease or health-related condition (e.g., high blood pressure)."[6]

The FDA evaluates the totality of scientific evidence and would agree with the claims only having determined that the evidence is in "significant scientific agreement." The guidance document for industry[7] lists the different types of evidence in order of their strength. Human interventional studies are at the top, then observational studies, then research synthesis studies (reviews and meta -analysis), with animal and *in vitro* studies at the bottom. The guidance document clearly states, "Before the strength of the evidence for a substance/disease relationship can be assessed, FDA separates individual relevant articles on human studies from other types of data and information. FDA intends to focus its review *primarily on articles reporting human intervention and observational studies because only such studies can provide evidence from which scientific conclusions can be drawn about the substance/disease relationship in humans"* [*emphasis added*]. Furthermore, the agency

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[4]EFSA. (n.d.). General scientific guidance for stakeholders on health claim applications. Chapter 6.2. Claims other than those based on the essentiality of nutrients. https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efs a.2016.4367

[5]FDA. (2009, January). Guidance for industry: Evidence-based review system for the scientific evaluation of health claims. https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm073332.htm

[6]FDA. (2018, January 12). Authorized health claims that meet the significant scientific agreement (SSA) standard. https://www.fda.gov/food/food-labeling-nutrition/authorized-health-claims-meet-significant-scientific-agreement-ssa-standard

[7]FDA. (2009, January). Guidance for industry: Evidence-based review system for the scientific evaluation of health claims. https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm073332.htm

states, "FDA intends to use animal and *in vitro* studies as background information regarding mechanisms that might be involved in any relationship between the substance and disease. *The physiology of animals is different than that of humans. … [T]hese studies do not provide information from which scientific conclusions can be drawn regarding a relationship between the substance and disease in humans"* [*emphasis added*]. Sections III(D) and (E) of the guidance document outline methods for evaluating and assessing the quality of studies, and only human studies are discussed. Section III(F) outlines methods for evaluating the totality of scientific evidence, and animal studies are not even mentioned.

The FDA does not require animal tests or accept animal data as stand-alone evidence for establishing health claims for foods.

Canada

The Food Directorate of Health Canada (FDHC) categorizes health claims as either disease risk reduction claims or function claims. A disease risk reduction claim is "a statement that links a food or constituent of a food to reducing the risk of developing a diet-related disease or condition" or a statement "about the treatment, or mitigation of a disease or health-related condition, or about restoring, correcting or modifying body functions." A function claim is "a statement about the specific beneficial effects that the consumption of a food or food constituent has on normal functions or biological activities of the body" or one that "describe[s] the well-established roles of energy or nutrients that are essential for the maintenance of good health or for normal growth and development."[8]

For both types of claim, Health Canada's requirements for study designs and evidence of interest are as follows:

> **a. Human Studies**
> Health Canada's evaluation of a health claim will be based on *human studies—intervention and/or prospective observational studies.* As such, the literature search strategy should be established with a focus on retrieving human studies. *The scientific uncertainties in extrapolating non -human data to humans limit the usefulness of non-human studies, such as animal and* in vitro *studies.* A submission guided by this document should thus be based on the retrieval and evaluation of human studies. If desired, non-human studies may be used to support the discussion on biological plausibility. This is, however, optional.
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> **b. Validity of Study Designs**
> The research design of human studies is a critical factor in interpreting the evidence for a health claim. Certain research designs can present biases that skew the interpretation of the evidence in an erroneous fashion and/or are not useful in inferring causality. Characteristics of research designs that limit the interpretation of the validity of the evidence are, for intervention studies, the absence of randomization and/or a control group. For observational studies, the use of retrospective studies

[8]Health Canada. (2016, May 17). Health claims. https://www.canada.ca/en/health-canada/services/food-nutrition/food-labelling/health-claims.html

(retrospective cohort, case-control), cross-sectional, and descriptive studies (ecologic, time series, demographic) does not allow determination of a causal relationship.

This document provides guidance on how human studies with different research designs should be dealt with. For intervention studies, non-randomized studies may be included during literature filtering; however, their subsequent quality rating will affect their contribution to supporting consistency. For observational studies, only those with a prospective design (i.e., prospective cohort and nested case -control studies) should be included; all other observational studies should be excluded.

Finally, if the subject of a health claim is a food constituent (i.e., not a food or a food category), the submission must at least include intervention studies; relevant observational studies would also be included, if available. Observational studies may be of greatest relevance for substantiation of health effects related to foods or food categories, but without intervention studies, observational studies alone generally do not allow for a causal inference to be made on the relationship between a food constituent and a health effect [*emphasis added*].[9]

FDHC does not require animal tests or accept animal data as stand-alone evidence for establishing health claims for foods.

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In summary, the EU, the US, and Canada all require human data —not animal data—to substantiate health claims for foods. Their agencies consider animal data as part of the totality of evidence but not as sufficient on its own. Some of the regulations also contain clear statements stressing the poor applicability of animal data to humans.

[9]Health Canada. (2009, March 17). Guidance document for preparing a submission for food health claims. Chapter 1.5: Study Designs and Evidence of Interest https://www.canada.ca/en/health-canada/services/food-nutrition/legislation-guidelines/guidance-documents/guidance-document-preparing-submission-food-health-claims -2009-1.html#a1-5