

The Scientific Assessment of Health Claims— When Only The Best Will Do

Introduction

Food and/or food constituents play a crucial role in health promotion and reduction of risk of major diseases as established through scientific evidence. A powerful form of conveying information on the potential health benefits of foods and food constituents is through making health claims in accompanying communications. Such claims could enhance the knowledge of nutrition and health among consumers¹⁻² and improve public health. In response to increased consumer interest in foods and food constituents with potential health benefits, regulatory bodies in several countries have developed guidelines for assessing health claims on foods and food constituents.

The Nutrition and Health Claims Regulation on Foods in the EU— A Brief Overview

In 2007, a regulation on nutrition and health claims made on foods was introduced in the European Union³ (hereafter referred to as the HCR). The HCR defines a “health claim” as “any claim that states, suggests or implies that a relationship exists between a food category a food or one of its constituents and health. The HCR allows two types of health claims to be made on foods/food constituents:

Article 13 of the HCR covers Health Claims other than those referring to reduction of disease risk or children’s health. These are health claims that refer to:

- (a) the role of a nutrient in growth, development and the functions of the body
- (b) psychological and behavioral functions
- (c) slimming or weight control.

Included under Article 13(5) are claims based on newly developed scientific data or which include a request for the protection of data.

Article 14 of the HCR covers Health Claims that refer to reduction of disease risk or children’s health. The HCR defines reduction of disease risk claim as “any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease.” All claims have to comply with the general principles that they are not false, ambiguous or misleading (as laid down in article 3), and they have to be scientifically substantiated (article 6).

The Recent Assessment of Health Claims in Europe – How Scientific is it?

The HCR also describes a process for the approval of the two types of health claims described above. Article 13 health claims (except those covered by Article 13(5)) will have to be based on “generally accepted scientific evidence” and have to be submitted to the EC for approval based on a list of relevant scientific references. Health claims covered by Article 13(5) and Article 14 will require dossiers of scientific evidence for these claims to be submitted to the EC for approval. The EC has forwarded the Article 13 lists as well as the Article 13(5) and Article 14 dossiers to the European Food Safety Authority (EFSA) for its scientific opinion.

In the Terms of Reference (ToR) for evaluating Article 13 health claims, provided by the European Commission to EFSA on 24 July, 2008, the Commission explicitly requests that EFSA shall evaluate the *extent to which the claimed*

effect of the food in the identified function is beneficial. Also, in assessing scientific evidence based on generally accepted science by taking the totality of scientific data into account and weighing the evidence, EFSA is invited to *comment on the nature and quality of the totality of the (scientific) evidence provided according to consistent criteria.*

However, several shortcomings have been observed in the scientific evaluations and opinions on health claims released by EFSA to date. Importantly, EFSA has: (1) failed to provide a grading of the 'strength of evidence' when assessing the relationship between food/food constituents and health; (2) omitted providing a clear definition of what it considers "generally accepted science;" (3) omitted clearly defining the standards it will apply in assessing the evidence from individual scientific studies (eg. what standards are applied in assessing biomarkers and surrogate end-points used in individual studies); (4) provided excessive emphasis on evidence from human intervention randomized-controlled trials (RCTs) in assessing relationship between food/food constituents and health and risk of disease. In doing so, EFSA has unfortunately failed to achieve the highest possible standards of scientific review.

Scientific Assessment of Health Claims – Fine-Tuning the Process

It is critical that the large body of established and emerging scientific evidence of the role of diet and certain specific food constituents in promoting health and reducing risk of chronic diseases is accurately and effectively relayed to the consumers to enable improvement of public health.

One important aspect of evaluating the scientific evidence substantiating health claims is providing a clear rating of its strength. It is with this goal in

mind that the World Health Organization (WHO) developed a grading system to evaluate the strength of the scientific evidence for the relationship between a food/food constituent and health.⁴ Evidence is classified into four grades based on its totality, as well as on the quality and consistency of individual studies. Importance is also given to regular review and updating of the classification based on emerging science. A similar method is also applied by the World Cancer Research Fund (WCRF)⁵ and advocated in the PASSCLAIM report.⁶ Application of such established methods by EFSA in the scientific evaluation of health claims would increase transparency of the process by clearly showing what individual studies were evaluated to provide the ranking as well as the rigor of the evaluation. It would also enhance consistency since such a grading system would allow other trained scientists to come to similar conclusions using the same database, while a regular review of the grading would give room for emerging science.

In assessing the quality of individual scientific studies supporting health claims, the type of study that has been conducted (ie. whether it is an observational study or a randomized controlled trial or an animal study) is highly relevant. Both the WHO and WCRF in their scientific evidence grading system describe evidence as being "convincing" when it is based on several high-quality studies of more than one type with consistency and biological plausibility. Numerous scientific publications have criticized excessive reliance on evidence from randomized controlled trials (RCTs) alone, and have suggested a well-rounded approach using evidence from both human observational-epidemiological studies and interventional studies, as well as supportive evidence from mechanistic studies to draw con-

clusions on the association between food/food constituents and health.⁷⁻¹⁰ In its report titled Evolution of Evidence for Selected Nutrient Disease Relationship,¹¹ the Institute of Medicine observes that RCTs appear to be less successful in investigating benefits of single nutrients in reducing risk of chronic diseases since chronic diseases develop over a long period of time and may be affected by various other factors at different times during that period.

Another essential aspect in assessing scientific evidence substantiating health claims is setting and defining a clear standard the degree of scientific agreement. In the United States, the Food and Drug Administration requires that scientific evidence substantiating health claims has to be based on 'significant scientific agreement', which the FDA defines as "an authoritative statement from a scientific body of the United States Government or the National Academy of Sciences."¹² Setting such clear standards also becomes important when evaluating the quality of individual scientific studies. For example, there are several biomarkers backed by scientific studies that can be used as surrogate end-points for risk of a specific disease. Additionally, biomarkers of specific food constituent intake are often based on food recall records and food composition tables. In the absence of clearly-defined and validated standards in either of the above cases, the evaluation of the quality of a study becomes vague and questionable. Clarification of the term "generally accepted science" by EFSA, as well as specification of the standards or benchmarks against which quality of individual studies will be evaluated would lead to consistency in the quality of the studies, and hence avoid any ambiguity in their evaluation and maintain uniformity in the health claim assessment process.

The relationship between diet and health has been strongly established by science. EFSA has been given the challenging task of validating the science and thereby determining the crucial message (claim) that will be relayed to the millions of consumers in Europe with impact on their health, safety and well-being. It is therefore upto EFSA to ensure that it applies no less than the highest possible scientific standards in every step of the process.

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