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Health claims made on food in the EU: The edge between scientific knowledge and regulatory requirements

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ABSTRACT

Background: The Health Claims Regulation entered into force in January 2007. The European Food Safety Authority (EFSA) has evaluated more than 3000 health claims since then, but EFSA's responsibilities in this area and the extent to which its scientific assessments are in accordance with the current legal framework are still not fully understood.

Scope and approach: The scope of this paper is to provide insight on the use of scientific knowledge in the area of nutrition for the substantiation of health claims made on food. The reasons why a positive evaluation by EFSA may not be sufficient for the authorisation of a health claim are also discussed. Concrete examples are used to illustrate these aspects.

Key findings and conclusions: How health claims are scientifically assessed by EFSA has not been fully understood by stakeholders yet. Thorough knowledge on how EU legislation translates into scientific requirements for substantiation is essential to building successful applications. Other factors which may play a role in the authorisation of a claim and which are not evaluated by EFSA, such as the legal status of the food/constituent, its safety, or the compatibility of the claim with national and international dietary recommendations, should also be considered early in the process. EFSA is committed to providing further guidance to stakeholders on how to prepare applications for authorisation by making use of its 10 years of experience on the scientific evaluation of health claims made on food.

1. Introduction

Regulation (EC) No 1924/2006 on nutrition and health claims made on foods (hereafter, the Health Claims Regulation, HCR) entered into force in January 2007 and applies from 1 July 2007. As of 9 June 2016, the European Food Safety Authority (EFSA) has evaluated about 2849 function claims under Article 13(1), 137 claims under Article 13(5), and 121 claims under Article 14, of which 41 fell under the scope of disease risk reduction claims.

The Article 13(1) procedure, originally meant as an evaluation of well-established functions of nutrients and other substances, proved to be challenging for all parties involved. On the one hand, the scientific requirements for the substantiation of health claims to be applied by EFSA had not been spelt out at the time food business operators (FBOs) had to submit the scientific evidence in support of their claims. On the other hand, several claims used for consumer communication were not framed to allow a scientific evaluation, and the procedure did not allow direct communication between EFSA and FBOs to better define such claims.

Nevertheless, the evaluation of health claims under Article 13(1) was an intense learning experience for EFSA, FBO and risk managers. It helped to clarify the criteria applied by the EFSA expert Panel on Dietetic Products, Nutrition and Allergies (NDA Panel) for the evaluation of claims, the criteria that claims had to comply with to allow a scientific evaluation, and some other aspects which risk managers could consider in the authorisation process. The result was a list of authorised, and a list of rejected, health claims (European Commission, 2016), and a series of guidance documents aiming to help FBOs in preparing applications under Articles 13(5) and 14 (EFSA, 2016a). Still, stakeholder meetings (EFSA, 2014a), public consultations on guidance documents (EFSA, 2016b) and direct communication between EFSA and FBOs during the life cycle of applications revealed some misunderstanding with respect to EFSA's remit, and questioned the extent to which the scientific assessments of the NDA Panel were in accordance with the legal framework set by the HCR.

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Acronyms

CHD	Coronary Heart Disease
EFSA	European Food Safety Authority
FBOs	Food Business Operators
HCR	Health Claims Regulation
NDA Panel	Expert Panel on Dietetic Products, Nutrition and Allergies

The most recently published General scientific guidance for stakeholders on health claim applications (EFSA NDA Panel, 2016a) summarises 10 years of experience in this area. It goes some steps beyond the previous guidance issued by the NDA Panel and spells out the scientific reading of a legal text which delineates a clear separation between the scientific assessment of health claims and their authorisation.

This paper aims to provide further insight into when, how, and why sound scientific knowledge in the area of nutrition can (or cannot) be used for the scientific substantiation of health claims made on food within the boundaries of the current legal framework. It also aims to explore why, and in which circumstances, a positive evaluation by EFSA may not be sufficient to allow the authorisation of a claim for use in the Community.

2. Legal context

The legal basis for EFSA's scientific evaluation of health claims is the HCR, which is consistent with the broader legal framework outlined by the general principles and requirements of food law (Regulation (EC) No 178/2002) and the general provisions relating to the labelling, presentation and advertising of foodstuffs (Directive 2000/13/EC; Regulation (EU) No 1169/2011).

Under the HCR, medicinal claims on food (i.e. claims attributing to any food the property of preventing, treating or curing a human disease) are forbidden, whereas reduction of disease risk claims (i.e. any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents (hereafter generically denoted as food/constituent) significantly reduces a risk factor in the development of a human disease) are allowed. In addition, food information provided on a voluntary basis shall not be ambiguous or confusing, shall not mislead the consumer, and shall be based on relevant scientific data. Nutrition and health claims are among the voluntary information which FBOs can use in commercial communications to help consumers in making informed food choices. Thus, any health claim made on foods shall be based on relevant scientific data (i.e. on a scientific assessment of the highest possible standard, as specified in the HCR) so as not to mislead the consumer. The HCR does not apply to claims which are made in non-commercial communications, such as dietary guidelines, advice issued by public health authorities and bodies, or scientific publications (Recital (4)).

Health claims, therefore, may be made on commercial communications to inform consumers on the relationship between the consumption of a food/constituent and a specific health benefit if: a) they do not attribute medicinal properties to a food, b) are based on a scientific assessment of the highest possible standard, and c) do not mislead the purchaser.

3. Translation of regulatory requirements into scientific requirements

The scientific assessment of health claims made on food needs an ad-hoc, well-defined and scientifically sound framework, the characteristics of which are not defined in the legal texts regulating the use of such claims. Nevertheless, literal readings of the HCR have been used (i.e. in public consultations on guidance documents, in stakeholder meetings, in the media) to question the scientific reasons given by the NDA Panel for favourable and unfavourable opinions, which indicates that a common understanding of how health claims are scientifically assessed by EFSA has not yet been reached.

This section addresses how the NDA Panel, in consultation with the European Commission, has interpreted the regulatory requirements for health claims made on food, and how this interpretation has been translated into scientific requirements for substantiation (Table 1).

3.1. The purchaser cannot be mislead

European legislation prohibits the use of information that would mislead the consumer in particular as to the characteristics of the food, its effects or its properties (Table 1). In other words, a consumer buying a food product which claims a particular health benefit should have a reasonable chance of obtaining such benefit when consuming the product on a regular basis in the recommended amounts.

From a scientific point of view, causality should be established between the consumption of a food/constituent and the claimed health benefit in the target population (i.e. the consumer buying the food to obtain the benefit) under the proposed conditions of use (i.e. in the recommended amounts and pattern of consumption). Human intervention studies, and in particular randomised controlled trials at low risk of bias, provide the best possible evidence on causality. Questions may remain on whether the effect observed in a (generally small) study group under controlled conditions would also occur on each and every free-living consumer. Indeed, people respond differently to different stimuli, including food, and free-living individuals may be eating the food less frequently or in lower amounts than they should to obtain the effect. Despite these limitations, this type of study design is the best placed to answer the question which matters: would the effect generally occur if the food/constituent is consumed by the target population in the recommended amounts?

Observational prospective cohort studies investigating the relationship between food consumption and the risk of disease have been published in high-quality scientific journals. These studies, often enrolling thousands of individuals and running for several years, have informed dietary guidelines and recommendations for the general population with the aim of maintaining good health in the long term. Some aspects of these guidelines are hardly disputed, such as the frequent consumption of fruits and vegetables. It may seem unreasonable, then, not to consider such prospective cohort studies as evidence to substantiate health claims, for example, on fruit, but there are at least two good reasons why this might be the case. First, people eating high amounts of fruits and vegetables may be at lower risk of disease than individuals consuming less fruits and vegetables for reasons other than their fruit and vegetable consumption, for example because they might also be physically more active, smoke less, or because they differ from their counterparts in other characteristics which affect the risk of disease and are unknown to the investigators. In other words, these studies do not allow causality to be established between the consumption of fruits and vegetables and disease risk.

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