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Review

Status of nutrition and health claims in Europe by mid 2015[☆]

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ABSTRACT

Background: Functional foods are closely associated with claims on foods. There are two categories of claims on foods: nutrition claims and health claims. Nutrition claims refer to what a food contains and comprise content claims and comparative claims. Health claims refer to what a food does and refer to general function claims, claims related to a reduction of risk of disease and claims related to the growth and development of children.

Scope and approach: Health claims on (functional) foods must be scientifically substantiated. In December 2006, the European Union published Regulation 1924/2006 on nutrition and health claims made on foods. The European Food Safety Authority (EFSA) provides the scientific advice to the European Commission for health claims submitted under Regulation 1924/2006. By 2015, EFSA has evaluated around 3000 health claims.

Key findings and conclusions: The outcome of the scientific evaluation process was that ca 250 health claims have been evaluated with a positive outcome, a few with insufficient evidence, whereas the large majority of health claims proposals were evaluated with the conclusion that the claim was not supported by scientific evidence. In addition to hundreds of opinions on health claims, EFSA has published various guidelines related to the scientific substantiation of health claims on foods and guidance documents for health claims related to diverse health endpoints. Upon scientific evaluation by EFSA, it is up to the European Commission and the member States to decide on authorisation. EU Regulation 432/2012 has established a list of general function claims under article 13 of Regulation 1924/2006.

Most health claims that have been approved and authorised are in the area of general functions claims for vitamins, minerals and other nutrients. EFSA hitherto has not found sufficient scientific support for health claims on microorganisms except for lactose digestion by yoghurt bacteria, and only a few on “antioxidants”. There are several substantiated health claims in the area of fibres and oligosaccharides. As from 14 December 2012, all claims that are not authorised or on hold/under consideration are prohibited.

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1. Introduction

On the one hand, nutrition, diet and foods can be major determinants underlying chronic diseases such as obesity, diabetes, cardio-vascular disease, and cancer (WHO, 2002, 2003, 2004). On the other hand, nutrition can significantly improve health. In addition to under-nutrition, over-nutrition and malnutrition, food safety is an inherent aspect associated with food and nutrition. In modern societies, the safety of foods is now essentially well

controlled. In the European Union (EU), the general policy on food safety has been laid down in the EU White Paper on Food Safety (European Commission, 2000). The European Food Safety Authority (EFSA (EFSA, 2015b)), along with its national counterparts, is deeply involved in scientific advice aimed at securing food safety. As such, food and diet can significantly contribute to public health in a beneficial and/or adverse way.

Interest in healthy food and diet encompasses the generation of foods with improvements on reducing negative aspects (e.g. lower in calories, sugar, sodium) as well as the incorporation of beneficial nutrients and ingredients (e.g. vitamins, minerals and other ingredients such as phytosterols/-stanols, microorganisms, fibres and oligosaccharides). This double focus on healthy eating has been a trigger for new developments in the food industry: functional

[☆] This paper is an update of papers published before: (Verhagen, 2008; Verhagen, Vos, Francl, Heinonen, & van Loveren, 2010).

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foods. In the 20th century, foods with health claims were first introduced in Japan. Thereafter, they were also introduced in the USA, Europe and the rest of the world. As such, functional foods comprise foods in which the composition of ingredients has been changed by addition, deletion or modification of ingredients. Functional foods are therefore the prime candidates to bear nutrition and health claims. A claim on foods distinguishes between functional foods and regular foods. Because initially there was little, if any, legal framework to control nutrition and/or health claims made on foods and many an exaggerated claim was made, the EU in 2006, after extensive debates, published its EU Regulation 1924/2006 on nutrition and health claims made on foods (EuropeanCommission, 2006a).

As regards regulatory aspects, the general *objective* of the Regulation 1924/2006 (EuropeanCommission, 2006a) is to harmonise the national rules on nutrition and health claims. In doing so, the Regulation 1924/2006 (EuropeanCommission, 2006a) starts with the notion that “An increasing number of foods labelled and advertised in the Community bear nutrition and health claims. In order to ensure a high level of protection for consumers and to facilitate their choice, products put on the market, including imported products, should be safe and adequately labelled. A varied and balanced diet is a prerequisite for good health and single products have a relative importance in the context of the total diet”. In addition, Regulation 1924/2006 aims to allow consumers to choose products in full knowledge of the facts and to ensure fair competition. The *scope* of Regulation 1924/2006 (EuropeanCommission, 2006a) encompasses all aspects of food products made in commercial communications to the final consumer: labelling, presentation, advertising as well as brand names, and trademarks. The *general principles* of Regulation 1924/2006 (EuropeanCommission, 2006a) are that claims shall: 1. Not be false, ambiguous nor misleading; 2. Not give rise to doubts as to the safety of nutritional adequacy of other foods; 3. Not encourage or condone excess consumption of a food; 4. Not state or suggest that a balanced and varied diet cannot provide for appropriate quantities of nutrients in general; 5. Not refer to changes in bodily functions which could create or exploit fear in consumers. In addition, the Regulation 1924/2006 (EuropeanCommission, 2006a) determines that these claims need to be based on and be substantiated by generally accepted scientific data, and by weighing the evidence. One very pivotal paragraph in Regulation 1924/2006 (EuropeanCommission, 2006a) is recital 23: “Health claims should only be authorised for use in the Community after a scientific assessment of the highest possible standard. In order to ensure harmonised scientific assessment of these claims, the European Food Safety Authority should carry out such assessments”, indicating the high scientific standard that must underlie the scientific substantiation of health claims.

2. EU Regulation 1924/2006 on nutrition and health claims made on foods

According to Regulation 1924/2006 (EuropeanCommission, 2006a), a *claim* is “any message or representation, which is not mandatory under Community or national legislation, including pictorial, graphic or symbolic representation, in any form, which states, suggests or implies that a food has particular characteristics” and a *health claim* is “any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health” or in shorter language “a *health claim* is any statement about a relationship between food and health” (EuropeanCommission, 2015c). Regulation 1924/2006 identifies two categories of claims on foods: nutrition claims and health claims (EuropeanCommission, 2006a; Flynn, 2012; Verhagen, 2008; Verhagen et al., 2010).

Nutrition claims are claims that state, suggest or imply that a

food has particular beneficial nutritional properties due to the energy it provides or the nutrients or other substances it contains. Examples hereof are content claims or comparative claims, e.g. “this product contains calcium” or “this product is low in sugar”. Explicit conditions are described in Regulation 1924/2006 (EuropeanCommission, 2006a) for claims such as “source of”, “high X”, “reduced fat”, “reduced energy”, “fat-free”. The Regulation allows for additions to this list (overview in Table 1).

There are three types of health claims in the EU (EuropeanCommission, 2015c); see also Fig. 1 and (EuropeanCommission, 2006a; Verhagen, 2008; Verhagen et al., 2010):

1. ‘Function Health Claims’ (or Article 13 claims):

- relating to the growth, development and functions of the body
- referring to psychological and behavioural functions
- on slimming or weight-control

2. ‘Risk Reduction Claims’ (or Article 14(1)(a) claims) on reducing a risk factor in the development of a disease. For example: “Plant stanol esters have been shown to reduce blood cholesterol. Blood cholesterol is a risk factor in the development of coronary heart disease”

3. Health ‘Claims referring to children’s development’ (Article 14(1)(b) claims). For example: “Vitamin D is needed for the normal growth and development of bone in children”

There is general consensus among scientists, consumers, authorities as well as industry that health claims on foods must be scientifically substantiated. This is at the interest of all stakeholders and contributes to fair trade. In the European Union there are several important developments; these cover scientific as well as regulatory aspects.

As regards the scientific aspects, a “Scientific and Technical Guidance for the preparation and presentation of the application for authorisation of a health claim” on foods was published by EFSA in 2007 and updated in 2011 (EFSA, 2011d); the health claim particulars as identified by EFSA are essentially similar to the scientific criteria identified in the earlier EU project PASSCLAIM (Aggett et al., 2005):

- All pertinent scientific data should be presented, both the studies that are in favour as well as the studies that are not in favour of the health claim, which will allow evaluating the totality of the scientific data and the subsequent weighing of the evidence.
- The characteristics of the food should be known.
- Human data are required to substantiate a health claim.
- Study group(s) should be used in the human studies that are representative of the target population for the health claim.
- It must be shown that the claimed effect is relevant for human health.
- The totality of the evidence must indicate that there is a causal relationship between consumption of the food and the health outcome in humans.
- It must be shown that the effect on health can reasonably be achieved as part of a balanced diet.

3. Regulatory environment related to nutrition and health claims

In the EU, nutrition and health claims made on foods are not only subject to the rules laid down in Regulation 1924/2006

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