International Journal of
Food Science & Technology

International Journal of Food Science and Technology 2015, **50**, 3–12

Review

Opportunities for product innovation using authorised European Union health claims

David P. Richardson[1]* & Manfred Eggersdorfer[2]

1 DPR Nutrition Ltd, 34 Grimwade Avenue, Croydon, Surrey CR0 5DG, UK
2 DSM Nutritional Products, P.O. Box 2676, 4002 Basel, Switzerland

(Received 5 February 2014; Accepted in revised form 9 April 2014)

Summary For authorisation of a health claim in Europe, applicants must follow the procedures in the legislation and in the guidelines for submission of a dossier, as well as the guidance in the European Food Safety Authority's opinions on the scientific requirements for health claims. In addition to the authorised functional benefits of the vitamins and minerals, certain foods and food constituents offer beneficial physiological effects that extend beyond traditionally accepted nutritional effects. The elucidation of these effects is becoming more important, as reflected by the increasing amount of nutrition research and number of product innovations. Provided that they are scientifically substantiated, health claims linked to food and food supplement products can help consumers make well-informed food choices. The present review focuses on scientific substantiation and consumer understanding of health claims, and it aims to help those involved in academic research, food product development and consumer education about food and health.

Keywords Beneficial physiological effects, food product innovation, health claims, scientific substantiation.

Introduction

The European Regulation on Nutrition and Health Claims Regulation (EC) No 1924/2006 (European Commission, 2006a) sets out the conditions of use and a system for the scientific evaluation of health claims, and it creates European Community lists of authorised claims. All claims have to comply with the general principles that they are not false, ambiguous or misleading, and scientifically substantiated health claims and reduction of risk of disease claims can be made for a food category, a food or one of its constituents based on an assessment of the totality of the available data and weighing of the evidence. A health claim is defined 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. A reduction of disease risk claim is defined 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. Health claims based on 'generally accepted' scientific evidence fall under Article 13.1, whereas those based on newly developed scientific evidence and/or where those claims include a request from the applicant for the protection of proprietary data fall under Article 13.5. Disease risk reduction claims and claims for children's development and health fall under Article 14.

Claims under Article 13.1 are based on diet and health relationships that are documented extensively in the scientific literature and for which there is general consensus in the scientific community. The application and authorisation procedures under Article 13.1 are now closed, and health claims in future applications must be made under Articles 13.5 and 14. Applicants for health claims must follow procedures set out in Regulation (EC) No 1924/2006 and in the implementing rules in Regulation (EC) No 353/2008 (European Commission, 2008), which include submission of a comprehensive dossier of scientific evidence, a proposal for the wording of the claim and specific conditions for its use. Nutrition and health claims are only permitted if they are scientifically justified and the average consumer can be expected to understand the beneficial effects as expressed in the claim. The average consumer is defined as one who is reasonably well informed and reasonably observant and circumspect, taking into account social, cultural and linguistic factors (Recital 16, Regulation (EC) 1924/2006).

*Correspondent: E-mail: info@dprnutrition.com

doi:10.1111/ijfs.12574

These laws in the European Union have influenced regulatory developments around the world, including the Codex Alimentarius Guidelines that set out a common approach for the substantiation of health claims, which is an important step towards global harmonisation (Codex Alimentarius Commission, 2009).

The purpose of the review is to explain how a health claim is assessed and authorised in the European Union, to provide strategic direction to researchers on what is considered by the European Food Safety Authority (EFSA) to be beneficial physiological effects, and to describe how the functional benefits of the essential micronutrients and other substances can provide opportunities for product innovation. In addition, the review refers to areas of the European regulations that are still being developed, including nutritional risk analysis for setting maximum levels of essential nutrients in foods with added nutrients and in food supplements, the establishment of nutrient profiles and the consumer understanding and communication of nutrition and health claims.

The role of European food safety authority

Regulation (EC) No 1924/2006 specified several significant tasks for EFSA including nutrient profiling and the scientific substantiation of health claims. These tasks proved to be the most challenging in terms of workload and complexity. The scientific opinions of the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA Panel) on the substantiation of health claims are used as the basis for authorisation decisions by the European Commission and Member States (with scrutiny by the European Parliament), and the lists of authorised and nonauthorised (prohibited) claims are published in the EU Register of Nutrition and Health Claims (http://ec.europa.eu/nuhclaims/). Based on experiences gained during the evaluation of health claims since 2008, and to assist applicants in preparing and submitting their applications for authorisation of health claims, the EFSA NDA Panel in 2011 and 2012 developed guidance documents on the scientific requirements for the substantiation of health claims related to:

- Gut and immune function (EFSA, 2011a)
- Antioxidants, oxidative damage and cardiovascular health (EFSA, 2011b)
- Appetite ratings, weight management and blood glucose concentrations (EFSA, 2012a)
- Bone, joints, skin and oral health (EFSA, 2012b)
- Nervous system, including psychological function (EFSA, 2012c)
- Physical performance (EFSA, 2012d)

These EFSA guidance documents define a range of claimed effects that are considered beneficial physiological effects under the Regulation and address the types of human studies, outcome measures and study groups considered to be appropriate for scientific substantiation of different health claims. EFSA requires sufficient evidence of cause and effect, and most of the successful outcomes of the scientific evaluations have focussed on foods and pure food constituents that are well characterised and for which beneficial physiological effects can be demonstrated by the use of human intervention studies with validated biomarkers. This rigorous approach is very difficult to achieve based on state-of-the-art nutrition science, and it poses significant challenges to make sure that the design, execution and interpretation of future human studies satisfy EFSA requirements (Richardson, 2012).

Physiological effects considered to be beneficial by European food safety authority

Many scientific opinions published by EFSA on the assessment of claims have listed numerous health effects that have been considered beneficial. Examples are given in Tables 1–6. For function claims, a beneficial effect may relate to the maintenance or improvement of a function. For reduction of disease risk claims, 'beneficial' refers to whether the claimed effect relates to the reduction (or beneficial alteration) of a risk factor for the development of a human disease (and not directly to the reduction of the risk of disease). A risk factor is a factor that is associated with the risk of a disease that may serve as a predictor of development of that disease. Whether or not the alteration of a factor is considered to be beneficial in the context of a reduction of disease risk claim depends on the extent to which it is established that:

- The factor is an independent predictor of disease risk (such a predictor may be established from intervention and/or observational studies).
- The relationship of the factor to the development of the disease is biologically plausible.

Each health claim or disease risk reduction claim is considered by the EFSA NDA Panel on a case-by-case basis, and the population group for which health claims are intended can be the general, healthy population or specific subgroups thereof, for example elderly people, physically active subjects, women of childbearing age. Reference to general, nonspecific benefits of the nutrient food for overall good health or health-related well-being may only be made if accompanied by a specific authorised health claim.

The EFSA scientific opinions provide guidance on whether the claimed effect is sufficiently defined to establish that the studies identified in the dossier for substantiation of the claim were performed with the

Table 1 Examples of physiological effects considered as beneficial by EFSA: gut and immune function (EFSA, 2011a)

Changes in bowel function such as reduced transit time, more frequent bowel movements, increased faecal or softer stools may be considered beneficial physiological effects, provided that they do not result in diarrhoea
Reducing gastrointestinal discomfort (e.g. distension/bloating, abdominal pain/cramp, rumbling in the absence of organic disease or biochemical abnormalities) is considered an indicator of improved gastrointestinal function and is regarded as a beneficial physiological effect
The presence of pathogenic microorganisms may cause infections at various sites in the body, and defence against pathogens at a specific site of the body is considered a beneficial physiological effect
For reduction of disease risk claims related to gastrointestinal infections, the presence of pathogens or toxins in the gastrointestinal tract is associated with the development of infections, and a relevant reduction of specific pathogenic microorganisms or their toxins in the gastrointestinal tract, as measured in suitable samples (e.g. stools), is considered a beneficial physiological effect in the context of reducing a risk factor for gastrointestinal infections
The EFSA NDA Panel concluded that the evidence available does not establish that increasing the number of any groups of microorganisms, including *Lactobacilli* and/or *Bifidobacteria*, is in itself a beneficial physiological effect. For function claims related to changes in gastrointestinal microbiota, these changes should be accompanied by a beneficial physiological or clinical outcome. This applies to both adult and infant/child populations
Improved digestion or absorption of nutrients might be considered as beneficial physiological effects
Maintaining normal immune function is a beneficial physiological effect
Resistance to allergens is a beneficial physiological effect
Chronic inflammation is associated with the development of a number of diseases, and altering levels of markers of inflammation might indicate a beneficial physiological effect in the context of a reduction of disease risk claim, if it can be demonstrated that altering the levels of inflammatory markers is accompanied by a reduced incidence of a disease for a specific dietary intervention

Table 2 Examples of physiological effects considered as beneficial by EFSA: antioxidants, oxidative damage and cardiovascular health (EFSA, 2011b)

The protection of body cells and molecules such as DNA, proteins and lipids from oxidative damage, including photo-oxidative (UV-induced) damage, may be a beneficial physiological effect
Maintenance of normal LDL cholesterol concentration is a beneficial physiological effect
Reduction in LDL cholesterol concentration within the normal range is considered a beneficial physiological effect in the context of a reduction of disease risk claim for CHD
Maintenance of normal HDL cholesterol concentration is a beneficial physiological effect as long as LDL cholesterol concentration is not increased
Maintenance of normal blood concentration of triglycerides may be a beneficial physiological effect
Maintenance of normal blood pressure is a beneficial physiological effect. Reduction in (systolic) blood pressure is considered beneficial in the context of a reduction of disease risk claim for CHD and stroke
An improvement of specific endothelial functions, for example endothelium-dependent vasodilation during sustained exposure (e.g. 4 weeks) to the food/constituent may be considered a beneficial physiological effect
Decreasing platelet aggregation in subjects with platelet activation during sustained exposure (e.g. 4 weeks) to the food/constituent would be a beneficial physiological effect
Maintenance of normal homocysteine metabolism is a beneficial physiological effect

Table 3 Examples of physiological effects considered as beneficial by EFSA: appetite ratings, weight management and blood glucose concentration (EFSA, 2012a)

The beneficial physiological effect of changing appetite ratings (e.g. hunger, fullness, satiety and desire to eat) depends on the context of the claim. For claims on changes in appetite ratings in the context of reducing bodyweight, evidence for a sustained effect with continuous consumption of the food should be provided
A sustained (intentional) reduction in total body fat is considered a beneficial physiological effect for adults in the general population with an excess of body fat
A sustained reduction in abdominal fat, and particularly in visceral fat, is considered a beneficial physiological effect for adults with adverse health effects associated with an excess of abdominal fat (e.g. impaired glucose tolerance, dyslipidaemia and high blood pressure)
A sustained increase in lean body mass may be a beneficial physiological effect for physically active subjects, including trained individuals. The maintenance (i.e. reduced loss of lean body mass) may also be beneficial, for example, during energy restriction leading to weight loss, or for older adults

Table 4 Examples of physiological effects considered as beneficial by EFSA: bone, joints, skin and oral health (EFSA, 2012b)

Contribution to the development and maintenance of normal bone throughout the lifespan is considered to be a beneficial physiological effect
Falling is considered as a risk factor for osteoporotic fractures, and reduction of the risk of falling is therefore a beneficial physiological effect by reducing the risk for osteoporotic fractures
Maintenance (i.e. reduced loss) of joint function can be considered a beneficial physiological effect
Changes in joint structure (e.g. changes in joint space width or other relevant measurements) leading to maintenance (i.e. reduced loss) of joint function(s) can be considered beneficial physiological effects
Plaque acid neutralisation or the reduction of acid production in dental plaque may prevent demineralisation and promote remineralisation of hydroxyapatite crystals, and are therefore considered a beneficial physiological effect
Reducing oral dryness is considered a beneficial physiological effect
Contribution to normal collagen formation is considered a beneficial physiological effect
Increasing net collagen formation, or reducing net collagen breakdown, leading to maintenance (i.e. reduced loss) of tissue function(s) (e.g. bones, cartilage, gums, skin, tendons and blood vessels) can be considered beneficial physiological effects
Changes in skin structure contributing to the maintenance (i.e. reduced loss) of skin function can be considered beneficial physiological effects
Maintenance (i.e. reduced loss) of the permeability barrier function of the skin protects the skin against dehydration and is considered to be a beneficial physiological effect
Protection of the skin (cells and molecules such as DNA, proteins and lipids) from oxidative damage, including photo-oxidative (UV-induced) damage, may be a beneficial physiological effect because any significant oxidative modification of the target molecules may lead to a change in function
Decreasing DNA damage after UV radiation exposure is considered a beneficial physiological effect, which can be measured directly in skin biopsies
Decreasing depletion of Langerhans cells after UV light exposure is considered a beneficial physiological effect, which can be measured directly in skin biopsies

Table 5 Examples of physiological effects considered as beneficial by EFSA: functions of the nervous system including psychological functions (EFSA, 2012c)

Improvement, maintenance or reduced loss of the functions of the nervous system is generally considered a beneficial physiological effect
Contribution to the normal development of the nervous system is considered a beneficial physiological effect
An increase, maintenance or reduced loss of cognitive function (e.g. several domains including memory, attention/concentration, alertness, learning, intelligence, language and problem solving) is a beneficial physiological effect
Contribution to the development of one or more specific domains of cognitive function in infants and small children is considered to be a beneficial physiological effect
Maintenance (i.e. reduced loss) of cognitive alertness is a beneficial physiological effect for subjects wishing to improve their level of alertness
Increase, maintenance or reduced loss of selective attention, sustained attention or both is considered to be a beneficial physiological effect
Improvement, maintenance or reduced loss of one or more cognitive processes related to memory is considered to be a beneficial physiological effect
Enhancement of mood/affect (i.e. increase, maintenance or reduced loss of one or more positive affect traits: enthusiasm and calmness, and decrease in one or more negative affect traits: confusion, feeling depressed, fatigue, tension and anxiety) is considered to be a beneficial physiological effect for subjects wishing to improve their mood
Alleviation of psychological stress (distress or tension) is a beneficial physiological effect
A reduction in anxiety (apprehensive anticipation of perceived danger or misfortune) is a beneficial physiological effect
An increase, maintenance or reduced loss of vision (e.g. improvement of visual adaptation to the dark) is a beneficial physiological effect for the general population
Maintenance or improvement of one or more aspects of sleep (e.g. time taken to fall asleep, sleep duration, ratio of total sleep time to total time in bed (sleep efficiency) and perceived quality of sleep (sleep quality)) is a beneficial physiological effect

appropriate outcome measures and/or validated biomarkers. The purpose of summarising the beneficial physiological effects in Tables 1–6 is to help researchers and applicants for health claims to identify key areas of normal metabolism that have already received attention by EFSA scientists, and to give strategic direction to universities and research institutes on the kind of studies and the biomarkers needed to achieve a positive outcome for the scientific substantiation of a health claim. Further guidance can be found on the design, conduct and reporting of human intervention studies to evaluate the health benefits of foods (Welch *et al.*, 2011) and on a standardised approach towards PROving the efficacy of foods and food constituents for health CLAIMs (PROCLAIM) (Gallagher *et al.*, 2011).

Table 6 Examples of physiological effects considered as beneficial by EFSA: physical performance (EFSA, 2012d)

Improvement, maintenance or reduced loss of physical performance may be a beneficial physiological effect for individuals performing physical exercise for different reasons, for example athletes preparing for a competition or during a competition, and individuals engaged in physical work or recreational activities, and also individuals performing common (non-exercise-related) physical tasks
Increased endurance capacity may be a beneficial physiological effect for individuals performing physical exercise that is not limited by time (e.g. recreational running, walking, swimming, cycling and fitness training)
Improvement, maintenance or reduced loss of muscle function (e.g. muscle strength) is considered a beneficial physiological effect
Changes in muscle structure (e.g. muscle mass, muscle shape, number and type of muscle fibres, muscle damage and muscle tissue repair) contributing to the improvement, maintenance or reduced loss of muscle function (e.g. muscle strength) can be considered a beneficial physiological effect
Faster recovery from water loss, muscle fatigue, muscle soreness or muscle damage after exercise contributing to the restoration of muscle function (e.g. muscle strength) can be considered a beneficial physiological effect

Table 7 Examples of well-established nutrient function claims that provide opportunities for product innovation

Functional benefit	Nutrient
Protection of cell constituents from oxidative damage	Vitamin C, vitamin E, copper, manganese, selenium and zinc
Contribution to a normal function of the immune system	Vitamin A (including beta-carotene), vitamin D, vitamin B_6, vitamin B_{12}, vitamin C, folic acid (folate), iron, copper, selenium and zinc
Contribution to the maintenance of normal bones and teeth	Calcium, vitamin D and phosphorus
Contribution to normal energy-yielding metabolism	Thiamin, riboflavin, niacin, vitamin B_{12}, biotin, pantothenic acid, vitamin C, copper, iron and magnesium
Contribution to the reduction of tiredness and fatigue	Niacin, vitamin B_6, vitamin B_{12}, pantothenic acid, vitamin C and magnesium
Contribution to the normal function of the nervous system; contribution to normal psychological functions	Biotin, vitamin B_6, vitamin C, niacin, vitamin B_{12}, iron and calcium

Functional benefits of the essential micronutrients and opportunities for product innovation

Vitamins and minerals have beneficial physiological effects that can be necessary for, and/or contribute to, the structure and functions of particular organs and several physiological states, for example reproduction, conception, growth and development and body maintenance. The well-established functions of vitamins and minerals are documented extensively in the scientific literature, and the establishment of a Community List of permitted claims is in the provisions of Regulation (EC) No 1924/2006. Under Article 13.1 of the Regulation, health claims can describe or refer to the role of a nutrient or other substance in growth, development and the functions of the body and those nutrients and substances that impact on psychological and behavioural functions. Details of the authorised health claims and the approved conditions of use are to be found in the EU register of nutrition and health claims available at http://ec.europa.eu/nuhclaims/.

Potential opportunities for product innovation relating to areas of health benefit are shown in Table 7.

Nutritional risk analysis and setting maximum levels of essential nutrients in foods with added nutrients and in food supplements

Eating a healthy, varied and balanced diet is a key message in all dietary recommendations and guidelines. However, national diet and nutrition surveys around the world continue to demonstrate areas of nutritional concern and population groups at risk of inadequate nutrient intakes and nutrient deficiencies. There are three complementary ways of safely delivering the essential vitamins and minerals for human health and well-being: (i) by promoting the consumption of nutrient-dense foods such as fruit and vegetables, wholegrain cereals, meat and dairy products, (ii) by increasing the availability and intake of foods with added nutrients (fortified foods) and (iii) by appropriate use of food (dietary) supplements. Regulatory authorities around the world need to ensure that levels of micronutrients in the total diet are safe and that the cumulative intake from all dietary sources does not lead to excessive intakes and any adverse effects in the population, including sensitive groups such as children, the elderly and women during pregnancy and lactation (Food and Agriculture Organisation/World Health Organisation, 2006).

Regulation (EC) No 1925/2006 (European Commission, 2006b), which makes provision for the harmonisation of the conditions for the voluntary addition of vitamins and minerals and of certain other substances to foods (referred to commonly as food fortification) and Directive 2002/46/EC (European Parliament and of the Council, 2002) on the approximation of the laws relating to food supplements, makes legal provisions for providing a high level of consumer protection and the setting of maximum amounts of the essential nutrients in fortified foods and food supplements. Because the vitamins and minerals are essential for life, the forthcoming regulatory developments in the European Union on setting maximum levels will have to take into account the fact that adverse effects can result from suboptimal intakes and deficiencies as well as from excessive intakes (Verkaik-Kloosterman *et al.* 2012). Recent literature, for example Elmadfa *et al.* (2009), Elmadfa & Freisling (2005), Flynn *et al.* (2009), Troesch *et al.* (2012) and Wahl *et al.* (2012), indicates that even with plenty of foods available, intake of certain vitamins and minerals in European countries does not meet recommendations. The Codex Alimentarius Nutritional Risk Analysis Principles and Guidelines (Codex Alimentarius Commission, 2010) set out the application of nutritional risk assessment and risk management approaches relating to the risk of adverse health effects from inadequate and/or excessive intakes of nutrients and related substances, as well as Codex proposed management strategies. In situations where inadequate intakes are addressed, a reduction in risk by dealing with the inadequacy is referred to as a nutritional benefit.

More recently, at the meeting of the 35th Codex Committee on Nutrition and Food for Special Dietary Uses (CCNFSDU) in November 2013, the general principles for the addition of essential nutrients to foods were discussed (Codex Alimentarius Commission, 2013). The provisional fundamental principles include the following:

Essential nutrients may be appropriately added to foods for the purpose of contributing to:

- Preventing/reducing the risk of, or correcting, a demonstrated deficiency of one or more essential nutrients in the population
- Reducing the risk of, or correcting, inadequate nutritional status or intakes of one or more essential nutrients in the population
- Meeting requirements and/or recommended intakes of one or more essential nutrients
- Maintaining or improving health
- Maintaining or improving the nutritional quality of foods.

These Codex Principles are intended to provide guidance to competent national or regional authorities to establish a basis for the rational and safe addition of essential nutrients to foods, and help guide food companies to develop and offer food items with optimised nutrient value.

Establishment of nutrient profiles

A remaining issue for product developers concerns Article 4 of Regulation (EC) No 1924/2006 (European Commission, 2006a) and the requirement to establish nutrient profiles taking into account:

- The quantities of certain nutrients and other substances contained in the food, such as fat, saturated fatty acids, trans fatty acids, sugars and salt/sodium
- The role and importance of the food (or food categories) and the contribution to the diet of the population in general or, as appropriate, of certain risk groups including children
- The overall nutritional composition of the food and the presence of nutrients that have been scientifically recognised as having an effect on health

The EFSA opinion (2008) addressed several key aspects including the choice and balance of nutrients to be taken into account, the choice of reference quantity, the basis of nutrient profiles (e.g. per 100 g, per quantified serving, per 100 kcal) and the approaches to the calculation of the profiles. The scientific and food policy challenges of developing a nutrient profiling system are substantial (Verhagen & van den Berg 2008). For scientists, it is how to establish a system based on objective scientific criteria. For food companies, it is how to use nutrient profiles for product innovation, for example for reducing fat, sugars or salt in products, while maintaining taste and quality. For consumers, it is how to use nutrient profiles and labelling to improve the daily diet and change dietary behaviour relative to lifestyle, age and potentially also to the individual genetic makeup. Future developments in this area will determine whether or not certain products will be able to use and make nutrition and health claims and the direction of investment in research and product innovation.

Examples of European authorised health claims

The clear objectives of the European legislation are to achieve a high degree of consumer protection, to ensure confidence in claims on foods by requiring that all health claims are scientifically substantiated, to improve free movement of goods and ensure fair competition and last but not least, to promote and protect innovation. Table 8 highlights the opportunities for a renaissance in food biosciences and multidisciplinary research and development.

Table 8 Opportunities for a renaissance for food biosciences

Identify beneficial interactions between the presence or absence of a food component and a specific function or functions in the body
Improve understanding of role of food and food components in maintaining and improving human health and in reducing the risk of major diseases
Establish science-/evidence-based approaches to underpin regulatory developments around the world on nutrition and health claims
Stimulate multidisciplinary research and development with biochemists, nutrition scientists, medical and healthcare professionals, food scientists and technologists
Reinvigorate efforts to process and preserve raw materials from agriculture, horticulture, fisheries and aquaculture into a diverse range of foods and food supplements

Authorisation of the health claim on the effect of water-soluble tomato concentrate on platelet aggregation pursuant to Article 13.5 of Regulation (EC) No 1924/2006

Following EFSA positive opinions on safety and efficacy of water-soluble tomato concentrate (WSTC), known commercially as 'Fruitflow™' (EFSA, 2009 and 2010a), there is an authorised European health claim, 'WSTC helps maintain normal platelet aggregation, which contributes to healthy blood flow'. This first Article 13.5 health claim was based on newly developed scientific evidence from several studies carried out at the Rowett Research Institute in Scotland and by Provexis Natural Products Limited. This lycopene-free, fat-free, low-sugar extract of tomatoes contains naturally occurring antiplatelet compounds that have been shown to suppress blood platelet activity in healthy people after consumption, thereby maintaining blood in a fluid and low coagulable state. This helps to maintain healthy blood flow, by preventing micro-aggregates forming within the circulation and by preventing the adherence of platelets to blood vessel walls or fatty plaques. The platelet function is not completely suppressed, and an appropriate level is maintained so that platelets can aggregate normally upon vascular injury and normal homeostatic balance is maintained for healthy vascular circulation.

The conditions of use for the two products forms of WSTC (I and II) are set out in European Commission Decisions of 17th December 2009 and 13th December 2010 to cover either fruit juices, flavoured drinks or yogurt drinks and food supplements, respectively (i.e. powdered single-serve sachets, tablets and capsules). The conditions of use of the health claims are 'Information to the consumer that the beneficial effect is obtained with a daily consumption of 3 g WSTC I or 150 mg WSTC II in up to 250 mL of either fruit juices, flavoured drinks or yogurt drinks (unless heavily pasteurised) or with a daily consumption of 3 g WSTC I or 150 mg WSTC II in food supplements when taken with a glass of water or other liquid'.

This basic scientific research to unlock the nutritional benefits of the Mediterranean diet and foods like tomatoes and its application in innovative food products illustrate well the opportunities for the development of new ranges of functional fruit-based beverages of interest to those consumers seeking to benefit the blood circulation and maintain cardiovascular health.

Authorisation of the health claim related to oat beta-glucan and lowering blood cholesterol and reduced risk of (coronary) heart disease pursuant to Article 14 of Regulation (EC) No 1924/2006

The EFSA NDA Panel concluded that a cause-and-effect relationship has been established between the consumption of oat beta-glucan and lowering of blood low-density lipoprotein (LDL) cholesterol concentration (EFSA, 2010b) and the permitted health claim, 'Oat beta-glucan has been shown to lower/reduce blood cholesterol. High blood cholesterol is a risk factor in the development of coronary heart disease', which was authorised by the European Commission in 2011. The substantiation of this disease risk reduction claim was based on a total of twenty-two references, which included three meta-analyses and nineteen randomised controlled human studies pertinent to the health claim. The target population is the adult general population and, in particular, people with an increased risk of hypercholesterolaemia who want to lower their blood cholesterol concentrations. The conditions of use of the claim are that 'Information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 3 g of oat beta-glucan' and 'The claim can be used for foods which provide at least 1 g oat beta-glucan per quantified portion'. This oat-specific Article 14 claim adds to the permitted Article 13.1 general claim, 'Beta-glucan contributes to maintenance of normal blood cholesterol concentrations'. The target population in this case is adults with normal or mildly elevated blood cholesterol concentrations.

Scientific opinion on the substantiation of a health claim related to increasing maternal folate status by supplemental folate intake and reduced risk of neural tube defects pursuant to Article 14 of Regulation (EC) No 1924/2006

In July 2013, the EFSA NDA Panel concluded that the association between low maternal folate intakes and an increased risk of neural tube defects (NTDs) is well established and that a recent systematic review showed an effect of maternal folic acid intakes on the risk of NTDs. The NDA Panel concluded that a cause-and-effect relationship has been established and that in order to obtain the claimed effect, 400 μg of supplemental folate should be consumed daily for at least 1 month before and up to 3 months after conception. The target population is women of childbearing age.

This positive EFSA opinion was issued on 26th July 2013 and a draft regulation (European Commission, 2013) authorising this Article 14 disease risk reduction claim was discussed on 18th November 2013 and on 5th December 2013 at the European Commission Standing Committee on the Food Chain and Animal Health. The authorisation procedure is likely to be completed by mid-2014.

All three examples of health claims illustrate the assessment approaches taken by the EFSA NDA Panel, namely STEP 1 to consider the extent to which:

- The food/constituent is defined and characterised.
- The claimed effect is defined and has a beneficial nutritional or physiological effect ('beneficial to human health').
- A cause-and-effect relationship is established between the consumption of the food/constituent and the claimed effect (for the target group under the proposed conditions of use); and

STEP 2, if a cause-and-effect relationship is considered to be established, whether:

- The quantity of food/pattern of consumption required to obtain the claimed effect can reasonably be consumed within a balanced diet.
- The proposed wording of the claim reflects the scientific evidence.
- The proposed wording of the claim complies with the criteria for the use of claims specified in Regulation (EC) No 1924/2006.
- The proposed conditions/restrictions of use are appropriate

The three examples also illustrate the opportunities for food and food supplement companies to collaborate with academia to stimulate basic research and innovative developments in food biosciences and food technology.

Consumer understanding and communication of nutrition and health claims

In the EU and around the world, the regulations governing nutrition and health claims are designed to protect consumers from misleading and false claims and to ensure confidence in claims on foods and food supplements. Claims should assist consumers to make informed choices and help them identify particular foods and food constituents as well as encouraging greater consumption of such foods as part of a varied and balanced diet and a healthy lifestyle. From an industry perspective, claims are used to identify, market and promote products, and as such, the claims are potentially powerful tools in communication to consumers because they convey information on food characteristics (e.g. a source of vitamin D and calcium) and health benefits that might otherwise remain unknown to the consumer (e.g. calcium and vitamin D are needed for the maintenance of normal bones and teeth).

The use of validated and authorised claims on foods and food supplements is likely to become widespread and, applied correctly, such claims present an opportunity to improve consumers' nutritional knowledge and healthy eating patterns, as well as contributing to public health more generally (Leathwood *et al.* 2007; Van Trijp, 2008; Wills *et al.* 2012).

An essential part of Regulation (EC) No 1924/2006, laid down in Article 5.2, is the statement, 'The use of nutrition and health claims should only be permitted if the average consumer can be expected to understand the beneficial effects as expressed in the claim'. With regard to general consumer understanding of health claims, data are scarce. However, Wills *et al.* (2012) undertook a comprehensive review of the state of research on how consumers respond to health claims on food and drink products, their attitudes to health claims and the products carrying them, their understanding of the health claims as well as their purchasing intentions for foods with health claims on them. Consumers are easily confused by detail and scientific wording of nutrition and health claim information, and as consumers process information, the meanings may easily go beyond the literal or even the intended meaning conveyed in the claim (Leathwood *et al.*, 2007). A consistent finding is that consumers prefer simple and easy to understand information on front of pack, with more detailed provided on back of pack (Roe *et al.*, 1999; Williams, 2005). The presence of a claim, a logo or an endorsement can also lead to a more positive interpretation of the product carrying the claim.

The field of consumer understanding of nutrition and health claims is in need for further research and development (Verhagen *et al.*, 2010). In the regulated health claims, wordings are first of all determined by the totality of the available scientific data collected

during the process of substantiation of health claims (Richardson, 2012). However, many terms such as 'normal metabolism', 'connective tissues', 'inhibition of platelet aggregation' can be difficult or impossible for consumers to understand. Consumer understanding of the strength and consistency of the scientific evidence contained in health claims is also still under debate in the EU, USA and other parts of the world. Clearly, there is much more research needed into how consumers interpret claims, and the challenge is how to translate accurately the scientific wording of the nutritional benefit into consumer language (Urala *et al.*, 2003). There is also a need for communication and education on healthy lifestyle and the role of foods with health claims. Close cooperation is required by regulatory bodies, governmental organisations, academia, consumer organisations and the food industry.

Conclusions

The European and indeed global developments reflect the fact that foods and food supplements with health claims are aimed primarily at the normal healthy population or population subgroups who wish to optimise their nutritional status and/or to reduce the likelihood of getting a particular chronic disease in later life. The legislation also recognises that the cause of chronic noncommunicable disease is multifactorial and includes genetic, behavioural and environmental factors as well as dietary factors. Hence, health claims provide guidance and are only permitted in the context of a varied and balanced diet and a healthy lifestyle.

This paper explores the approaches to scientific substantiation of health claims on foods and food constituents based on the assessment of the totality of the available scientific data and weight of the evidence. Consumers should be able to make choices based on clear and accurate information and to have confidence in the scientific and regulatory processes used to support health claims. The concept that diet and particular foods and food constituents can have beneficial physiological and nutritional effects beyond widely accepted nutritional effects has been developed significantly in recent years. The paradigm shift from hunger satisfaction and adequacy of nutrition to optimum nutrition and delaying the onset and development of major diseases such as cardiovascular disease and osteoporosis can be proclaimed as a major stimulus for the food biosciences and food technology and a renaissance for scientific research on human nutrition.

References

Codex Alimentarius Commission (2009). Annex to the Codex Guidelines for the use of nutrition and health claims: recommendations on the scientific substantiation of health claims. CAC/GL 23-2007.

Codex Alimentarius Commission (2010). *Procedural Manual: Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the Committee on Nutrition and Foods for Special Dietary Uses*, 19th edn. Pp. 120–126. Section 4. Rome: WHO/FAO.

Codex Alimentarius Commission (2013). Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU). Proposed draft revision of the Codex General Principles for the Addition of Essential Nutrients to Foods. Consultation paper with summary of responses. CX/NFSDU 13/35/5, October/November 2013. 35th Session, Bad Soden am Taunus, Germany.

Elmadfa, I. & Freisling, H. (2005). Nutritional status in Europe. *Nutrition Reviews*, **67**(Suppl. 1), S130–S134.

Elmadfa, I., Meyer, A. & Nowak, V. (2009). European nutrition and health report. In: *Forum of Nutrition* (edited by I. Elmadfa). Vol. 62. Basel, Switzerland: Karger.

European Commission (2006a). Regulation (EC) No 1924/2006 on nutrition and health claims made on foods. *Official Journal of the European Union*, **404**, 3–18.

European Commission (2006b). Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20th December 2006 on the addition of vitamins and minerals and of certain other substances to foods. *Official Journal of the European Union*, **L404**, 26–38.

European Commission (2008). Commission Regulation EC No 353/2008 establishing implementing rules for applications for authorisation of health claims as provided for in Article 15 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council. 18th April 2008.

European Commission (2009). Commission Decision of 17th December 2009 authorising a health claim on the effect of water-soluble tomato concentrate on platelet aggregation and granting the protection of proprietary data under Regulation (EC) No 1924/2006 of the European Parliament and of the Council. *Official Journal of the European Union*, **L336**, 55–57.

European Commission (2010). Commission Decision of 13th December 2010 amending the Decision 2009/980/EU as regards the conditions of use of an authorised health claim on the effect of water-soluble tomato concentrate on platelet aggregation. *Official Journal of the European Union*, **L328**, 18–19.

European Commission (2013). Draft Commission Regulation on the authorisation of a health claim made on foods and referring to the reduction of disease risk (no citation reference available as of 28/01/2014).

European Food Safety Authority (2008). Scientific opinion of the Panel on Dietetic Products, Nutrition and Allergies (NDA) on the setting of nutrient profiles for foods bearing nutrition and health claims pursuant to Article 4 of the Regulation (EC) No 1924/2006. *EFSA Journal*, **644**, 1–44.

European Food Safety Authority (2009). Scientific opinion of the Panel on Dietetic Products, Nutrition and Allergies (NDA). Scientific substantiation of a health claim related to water-soluble tomato concentrate (WSTC I and II) and platelet aggregation pursuant to Article 13 (5) of Regulation (EC) No 1924/2006. *EFSA Journal*, **1105**, 1–15.

European Food Safety Authority (2010a). Scientific opinion of the Panel on Dietetic Products, Nutrition and Allergies (NDA) on the modification of the authorisation of a health claim related to water-soluble tomato concentrate and helps to maintain a healthy blood flow and benefits circulation pursuant to Article 13 (5) of Regulation (EC) No 1924/2006 following a request in accordance with Article 19 of the Regulation (EC) No 1924/2006. *EFSA Journal*, **8**, 1689.

European Food Safety Authority (2010b). Scientific opinion of the Panel on Dietetic Products, Nutrition and Allergies (NDA) on the substantiation of a health claim related to oat beta-glucan and lowering blood cholesterol and reduced risk of (coronary) heart disease pursuant to Article 14 of Regulation (EC) No 1924/2006. *EFSA Journal*, **8**, 1885.

European Food Safety Authority (2011a). Scientific opinion of the Panel on Dietetic Products, Nutrition and Allergies (NDA) on guidance on the scientific requirements for health claims related to gut and immune function. *EFSA Journal*, **9**, 1984.

European Food Safety Authority (2011b). Scientific opinion of the Panel on Dietetic Products, Nutrition and Allergies (NDA) on guidance on the scientific requirements for health claims related to antioxidants, oxidative damage and cardiovascular health. *EFSA Journal*, **9**, 2474.

European Food Safety Authority (2012a). Scientific opinion of the Panel on Dietetic Products, Nutrition and Allergies (NDA) on guidance on the scientific requirements for health claims related to appetite ratings, weight management, and blood glucose concentrations. *EFSA Journal*, **10**, 2604.

European Food Safety Authority (2012b). Scientific opinion of the Panel on Dietetic Products, Nutrition and Allergies (NDA) on guidance on the scientific requirements for health claims related to bone, joints, skin, and oral health. *EFSA Journal*, **10**, 2702.

European Food Safety Authority (2012c). Scientific opinion of the Panel on Dietetic Products, Nutrition and Allergies (NDA) on guidance on the scientific requirements for health claims related to functions of the nervous system, including psychological functions. *EFSA Journal*, **10**, 2816.

European Food Safety Authority (2012d). Scientific opinion of the Panel on Dietetic Products, Nutrition and Allergies (NDA) on guidance on the scientific requirements for health claims related to physical performance. *EFSA Journal*, **10**, 2817.

European Food Safety Authority (2013). Scientific opinion of the Panel on Dietetic Products, Nutrition and Allergies (NDA) on the substantiation of a health claim related to increasing maternal folate status by supplemental folate intake and reduced risk of neural tube defects pursuant to Article 14 of Regulation (EC) No 1924/2006. *EFSA Journal*, **11**, 3328.

European Parliament and of the Council (2002). Directive 2002/46/EC of the European Parliament and of the Council of 10th June 2002 on the approximation of the laws of the Member States relating to food supplements. *Official Journal of the European Communities*, **L183**, 51–57.

Flynn, A., Hirvonen, T., Mensinck, G.B.M. *et al.* (2009). Intake of selected nutrients from foods, from fortified foods and from supplements in various European countries. *Food & Nutrition Research*, **53**(Suppl. 1), 1–51.

Food and Agriculture Organisation/World Health Organisation (2006). A model for establishing upper levels of intake for nutrients and related substances. Report of a joint FAO/WHO Technical Workshop on Nutrient Risk Assessment, WHO Headquarters, Geneva, Switzerland, 2–6 May, 2005. Geneva: FAO/WHO.

Gallagher, A.M., Meijer, G.W., Richardson, D.P. *et al.* (2011). A standardised approach towards PROving the efficacy of foods and food constituents for health CLAIMs (PROCLAIM); providing guidance. *British Journal of Nutrition*, **106**, S16–S28.

Leathwood, P.D., Richardson, D.P., Sträter, P., Todd, P.M. & van Trijp, H.C. (2007). Consumer understanding of nutrition and health claims: sources of evidence. *British Journal of Nutrition*, **98**, 474–484.

Richardson, D.P. (2012). Nutrition and health claims: help or hindrance. Preparing dossiers: strength of the evidence and problems of proof. *Proceedings of the Nutrition Society*, **71**, 127–140.

Roe, B.E., Levy, A.S. & Derby, B.M. (1999). The impact of health claims on consumer research and product evaluation outcomes: results from FDA experimental data. *Journal of Public Policy & Marketing*, **18**, 89–105.

Troesch, B., Hoeft, B., McBurney, M., Eggersdorfer, M. & Weber, P. (2012). Dietary surveys indicate vitamin intakes below recommendations are common among representative Western countries. *British Journal of Nutrition*, **108**, 692–698.

Urala, N., Arvola, A. & Lahteenmaki, L. (2003). Strength of health-related claims and their perceived advantage. *International Journal of Food Science & Technology*, **38**, 815–826.

Van Trijp, H.C. (2008). Consumer understanding and nutritional communication: key issues in the context of the new EU legislation. *European Journal of Nutrition*, **48**(Suppl. 1), S41–S48.

Verhagen, H. & van den Berg, H. (2008). A simple visual model to compare existing nutrient profiling schemes. *Food and Nutrition Research*. doi: 10.3402/fnr.v52i0.1649.

Verhagen, H., Vos, E., Franci, S., Heinonen, M. & van Loveren, H. (2010). Status of nutrition and health claims in Europe. *Archives of Biochemistry and Biophysics*, **501**, 6–15.

Verkaik-Kloosterman, J., McCann, M.T., Hookstra, J. & Verhagen, H. (2012). Vitamins and minerals: issues associated with too low and too high population intakes. *Food and Nutrition Research*, **56**, 5728. http://dx.doi.org/10.3402/fnr.v56i0.5728.

Wahl, D.A., Cooper, C., Ebeling, P.R. *et al.* (2012). A global representation of vitamin B status in healthy populations. *Archives of Osteoporosis*, **7**, 155–172.

Welch, R.W., Antoine, J.-M., Berta, J.-L. *et al.* (2011). Guidelines for the design, conduct and reporting of human intervention studies to evaluate the health benefits of foods. *British Journal of Nutrition*, **106**, S16–S28.

Williams, P.G. (2005). Consumer understanding and use of health claims for foods. *Nutrition Reviews*, **63**, 256–264.

Wills, J.M., Storcksdieck Gennant Bonsmann, S., Kolka, M. & Grunert, K.G. (2012). European consumers and health claims: attitudes, understanding and purchasing behaviour. *Proceedings of the Nutrition Society*, **71**, 229–236.