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ORIGINAL ARTICLE

Nutrition and health claims: the role of food composition data

JL Buttriss and B Benelam

British Nutrition Foundation, London, UK

Regulation on nutrition and health claims number (EC) No. 1924/2006 came into force in the European Union (EU) in 2007. The Regulation aims to ensure that claims are truthful and do not mislead consumers. It also aims to stimulate innovation to produce healthier food products in the food industry. Nutrition claims are defined in an annex to the Regulation that states the wording of permitted claims and the conditions of use. The scientific support for potential health claims is being assessed by the European Food Safety Authority (EFSA), but consideration of other aspects and the final decision to accept or reject a claim lies with the European Commission. The final list of approved health claims was due to be published in early 2010, but work is behind schedule, and therefore decisions are being published in batches; the first batch of Article 13 claims based on generally accepted science was published in October 2009. Food composition data are vital in making accurate claims on food as the amount of the nutrient or food component in question must be defined. It is also important that the composition of a particular food or food category has been sufficiently defined in order for a health claim pertaining to this to be approved. In addition, to prevent claims being made on foods with a less healthy profile, nutrient profiles are being developed that will specify threshold amounts of saturated fat, sodium and sugar present in any product bearing a nutrition or health claim, and thus the composition of a food will be critical in determining whether it is eligible to carry a claim. Therefore, the access that the European Food Information Resource (EuroFIR) will provide to pan-European food composition data will be of great importance in making the Regulation workable. EuroFIR has been actively involved in EFSA's work on nutrient profiles, supplying data that have been used to develop the current profiling model. It is hoped that the EuroFIR Network and the not-for-profit organisation EuroFIR AISBL (Association Internationale Sans But Lucratif, that has been established to take forward EuroFIR's work) can continue to provide guidance to stakeholders as the Regulation develops.
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Introduction

European consumers are exposed to a wide variety of messages about the relationship between diet and health, and there is widespread interest in the nutritional content of food. Information about nutrition and health in the press can appear complex or conflicting, and it may not be clear to many consumers what the healthiest choice is when deciding which foods to buy. Helping consumers to choose a healthy diet is increasingly important in the European Union (EU) as the prevalence of obesity and related conditions such as type II diabetes, high blood pressure and cardiovascular disease are rising. Accurate and informative food labelling can have an important part in helping consumers to select the most appropriate foods when shopping to provide a healthy balanced diet. However, unclear or misleading information on food products can increase confusion and lead to mistrust of healthy eating messages.

Before the Regulation described below was introduced by the EC (European Commission) (2007), a number of voluntary schemes provided guidelines on nutrition and health claims in the EU and internationally, including the codes published in Sweden, in the Netherlands, the Joint Health Claims Initiative in the United Kingdom and guidelines from the Codex Alimentarius commission, part of the joint World Health Organisation/Food and Agriculture Organisation food standards programme. However, there was increasing concern that the variation in nutrition and health claims in the EU would lead to misleading claims and barriers to trade, and this provided the impetus in the EC to develop a new regulation.

Correspondence: Professor JL Buttriss, Director General, British Nutrition Foundation, High Holborn House, 52-54 High Holborn, London WC1V 6RQ, UK.
E-mail: j.buttriss@nutrition.org.uk

Regulation 1924/2006/EC on nutrition and health claims

The new Regulation on nutrition and health claims was agreed in December 2006 and is intended to complement the general principles laid down in the previous directives on labelling, and to work alongside other directives on foods for particular nutritional uses, the quality of drinking and mineral water, and on supplements. It applies to all nutrition and health claims made in commercial communications, that is, labelling, presentation or advertising of foods and supplements, and the intention is to provide a high level of consumer protection while allowing the EU market to function effectively. The Regulation covers any message or representation, including pictures and symbols that state, suggest or imply that a food has particular characteristics.

Overall, any claim made should be truthful and should not attempt to mislead consumers. Nor should it call into question the safety or nutritional content of other foods or the adequacy of a balanced diet. The claim itself must apply to the food as eaten, prepared according to the manufacturers instructions, and the effects described in the claim must be understandable to consumers. In order for a product to bear either a nutrition or a health claim, full nutritional labelling must be provided on the product (that is, energy, fat, saturates, carbohydrate, sugars, protein, dietary fibre and sodium). If information about the level of the food constituent referred to in the claim (for example, calcium or a vitamin) does not usually appear on a food label, the level of that constituent must also be stated alongside the other nutritional information.

The following definitions are provided in the Regulation:

- *Claim*—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.
- *Nutrition claim*—any claim that states, suggests or implies that a food has particular beneficial nutritional properties due to:
  - the energy (calorific value) it
    - provides
    - provides at a reduced or increased rate; or
    - does not provide and/or
  - the nutrients or other substances it
    - contains
    - contains in reduced or increased proportions; or
    - does not contain.
- *Health claim*—any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health.
- *Reduction of disease risk claim*—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 are divided into Article 13 and Article 14 claims. Article 13 health claims are those claims that do not refer to either the reduction of disease risk or to children's development and health.

Health claims under this article can describe or refer to:

- The role of a nutrient or other substance in growth, development and the functions of the body.
- Behavioural or psychological functions.
- Slimming, weight control, an increased sensation of satiety or the reduction in available energy from the diet.

If these claims are supported by generally accepted scientific evidence and are considered to be well understood by the majority of consumers, under the Regulation (Article 13.1) it is not necessary to compile a full dossier to gain authorisation. A list of such claims is being prepared, and to achieve this, food business operators have had the opportunity to submit the claim, together with supporting scientific substantiation in the form of scientific papers, to the competent authority in their country, who in turn has submitted a list of claims to the EC for scrutiny by the European Food Safety Authority (EFSA). However, Article 13 claims based on emerging evidence (covered in Article 13.5 of the Regulation) must be authorised via submission of a dossier of evidence for scrutiny by EFSA (see Figure 1).

Article 14 health claims are those concerning reduction of disease risk and those referring to children's development and health. These claims are also authorised via submission of a dossier of evidence.

In assessing each specific food/health relationship that forms the basis of a health claim, EFSA's NDA Panel considers the extent to which:

- the food/constituent is defined and characterised
- the claimed effect is defined and is a beneficial nutritional or physiological effect (in terms of 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, 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 reflects the scientific evidence
- the proposed wording complies with the criteria for the use of claims specified in the Regulation
- the proposed conditions/restrictions of use are appropriate.

EFSA applies the same basic process to the assessment of all health claims on a case-by-case basis, and therefore the detailed application of these steps may vary. For example, if the claim is product specific, studies with the product or directly relevant to it must be provided. In addition, an application may be strengthened if it can be shown that the

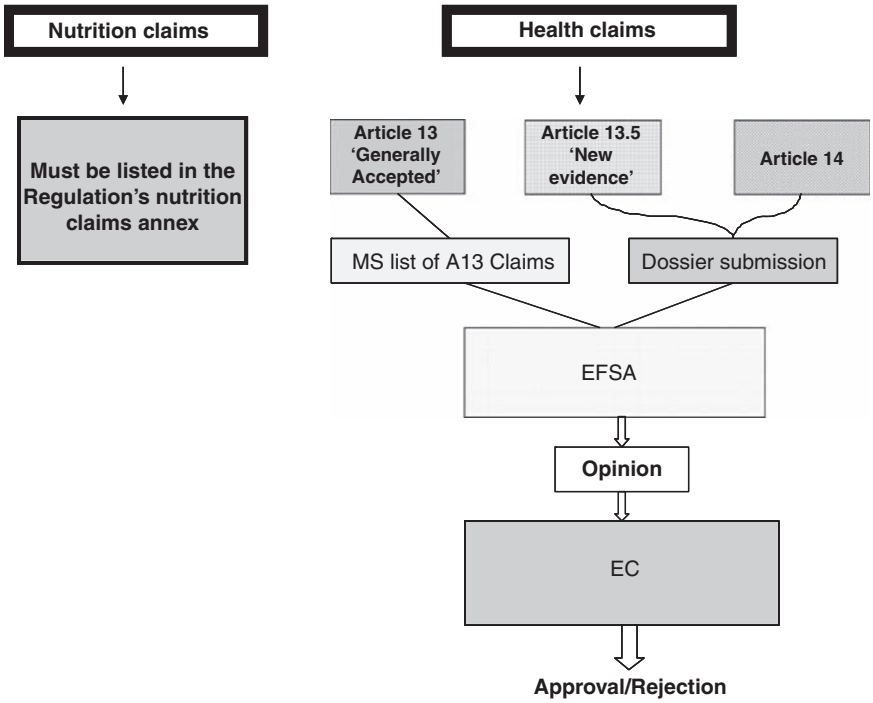

Figure 1 Summary of the claims approval process. EC, European Commission; EFSA, European Food Safety Authority; MS, member states.

target population may have suboptimal levels of the nutrient in question. Further details of the procedures followed by EFSA have been published recently (EFSA, 2009).

A system of nutrient profiling will be used in conjunction with this Regulation to ensure that claims do not mask the overall nutrient content of a product. If one nutrient threshold is exceeded, no health claims will be permitted but a nutrition claim could be made, although this would have to be qualified with a statement that the product is high in the nutrient that has exceeded the threshold (for example, 'high sugar content'). If more than one threshold is exceeded, neither nutrition nor health claims about the product will be allowed. The Commission hopes that this will encourage manufacturers to improve the nutritional characteristics of their products, making it easier for consumers to choose a healthy balanced diet. This profiling approach must balance the complex relationships between diet and health while being user friendly for stakeholders, such as food business operators and regulators. In early 2008, EFSA provided an opinion on the approach that should be adopted, at the request of the EC, but, as discussed later in this paper, the Commission has yet to publish a final scheme.

Importance of food composition data

Before any nutrition or health claim can be made on a food, it is essential to know its nutritional composition in order to verify that the constituent in question is present in sufficient quantities to make the claim relevant. As many food manufacturers calculate composition from food composition databases, these must be accurate, comprehensive and up-to-date. It is also possible that, in the future, health claims in the EU may expand to cover non-nutrient bioactive substances such as polyphenols from tea or lycopene in tomatoes, and therefore data will also be needed on these. In this case, specialised data sets, such as the European Food Information Resource (EuroFIR)-BASIS database on bioactive compounds in plants, which is being developed as part of the EuroFIR project, will be invaluable, as data on these are currently sparse. Indeed, this database will not only provide compositional information, but will also give details of evidence for the health benefits of these compounds.

EuroFIR is working closely with EFSA on the potential uses of the EuroFIR-BASIS bioactives database (on both compositional and biological effects) to support a number of tasks. The database may be used in the evaluation of genetically modified (GM) foods, as bioactive compounds in plants can be key in determining whether a GM plant is substantially different from the non-GM version, and whether any differences have the potential to be harmful. It could also be used to evaluate novel food applications and the evaluation of natural plant compounds used as ingredients or additives in foods. As mentioned above, the database is available for use by EFSA in the consideration of evidence for health claims involving plant bioactives and also in making new diet and health recommendations.

In addition, if, as it is hoped, the incentive of being able to display a nutrition or health claim on a product drives reformulation of foods, either to increase the content of beneficial constituents or to comply with a specified nutrient profile, there may be substantial changes in the composition of foods. The links that the EuroFIR network is building with the food industry to share food composition data with food composition database compilers will help to ensure that the data available keep up with these changes. EuroFIR is also working closely with CIAA (Confédération des industries agro-alimentaires, the European organisation that represents the interests of food manufacturers) to find ways to improve the flow of food composition data from industry to food composition databases.

Again, the availability of this information will be essential to EFSA in order to support its work on nutrient profiles of foods, health claims, exposure assessment and assessment of nutrient consumption across Europe. In order to deepen our understanding of the relationship between diet and health, we must be able to characterise the composition of the foods we eat and tease out the associations between dietary constituents and physiological effects.

Current situation

Nutrient profiles

In 2008 EFSA provided the EC with an opinion on the development of a nutrient profiling scheme to support the Nutrition and Health Claims Regulation, and the EC subsequently published for consultation a proposed profiling approach that focused on just three nutrients—saturated fatty acids, sugar and sodium, with thresholds for each derived from the World Health Organisation's dietary recommendations. A feature of the proposal was the combination of generic thresholds for most food categories alongside adapted thresholds or exemptions for a number of categories. The categories listed in the proposal were: vegetable oils; spreadable fats; dairy products; cereals and cereal products; fruits, vegetables and their products; meat and meat products; fish and fish products. In arriving at the proposal, EFSA and the EC used a 'basket' of food items considered to be representative of foods consumed in Europe to test the impact of a variety of threshold levels for the three nutrients. Although the final version of the profiling system was scheduled to be published in early 2009, to date (more than a year later) this has yet to happen.

Annex of nutrition claims

The process for making nutrition claims is relatively straightforward if the nutrient in question is included in the annex to the Regulation and the conditions of use are met, for example, at least 15% of the RDA (recommended daily amount) for a specific vitamin or mineral is provided per 100 g or 100 ml. However, some nutrients such as *n*-3 and *n*-6 fatty acids were not included in the original Regulations. The levels of *n*-3 and *n*-6 fatty acids that are required to be present in order to make a nutrition claim, and the wording of such claims has recently been agreed by the EC, but other nutrients and food components (for example, 'wholegrain') remain under discussion. Provision of claims on foods that are targeted at children is currently governed by the nutrient reference values derived for adults; the EC has been asked to consider setting specific values that are appropriate for the needs of children that could be used instead.

EFSA assessment and EC approval of health claims

Assessment of the scientific evidence to support health claims is the responsibility of EFSA. The Commission is responsible for ensuring that the claim will be well understood by consumers and also for the overall decision as to whether a particular claim will be allowed and any conditions of use.

In determining whether the evidence provided is pertinent to a claim, EFSA pays particular attention to the following points:

- studies that are central for substantiation of the claim should be human dietary studies
- whether the study addresses the food constituent that has been characterised in the application
- whether the study addresses endpoints that are relevant to the health relationship as defined in the application
- whether the study is within the target population indicated in the application or could be extrapolated to the target population
- whether the dosage and/or food matrix is relevant to the proposed conditions of use as defined by the application
- whether supportive studies in animals and *in vitro* are relevant for the claimed effect
- if the claim relates to a specific product, whether the studies submitted to support this claim use this product.

The human studies that meet these criteria together with any relevant supportive animal or *in vitro* studies are used as the basis on which substantiation is judged. Should this evidence point to a favourable opinion, EFSA also checks that the evidence provided by the applicant reflects the totality of the available evidence in the literature. Specific aspects of interest when identifying a causal effect are: consistent associations with outcome measures, plausible biological mechanisms, dose–response relationships, ability to manipulate the effect and specificity of cause and effect.

The first set of opinions on dossiers submitted for assessment of Article 14 and Article 13.5 claims were published on EFSA's website in August 2008. Of the eight claims assessed, only one received EFSA's approval; this related to the ability of plant sterols to lower blood cholesterol, thus reducing risk of cardiovascular disease. By October 2009, EFSA had received a total of 282 dossiers to evaluate (213 concerning children under Article 14; 47

disease reduction claims under Article 14; and 22 concerning new science under Article 13.5). At this point in time, a total of 73 opinions covering 80 applications had been published, almost 80% of which were rejections. Among the claims that were accepted (a total of 15, 10 of which related to children and 4 to disease reduction) was 'vitamin D is essential for the bone growth of children'. EFSA concluded that the studies showed good consensus on the role of vitamin D in bone growth, a cause and effect relationship was established, and there was evidence of low vitamin D status in subgroups of the target population. Any food carrying this claim should provide at least 15% of the RDA for vitamin D (that is, be a 'source' of the vitamin) and will have to comply with the nutrient profiles set for the category of food, once these have been agreed.

Other positive EFSA opinions on Article 14 health claims, to date, concern plant sterols/stanols and cholesterol reduction, xylitol and caries reduction, iron and cognitive development in children, α-linolenic acid and brain development in children, long-chain polyunsaturated fatty acids and visual development in children, and various claims related to bone growth in children.

During 2009, the EC and EFSA have also been reviewing the large number of potential Article 13.1 claims submitted via Member States—around 44 000 were submitted in all. This Article concerns claims for which there is 'generally accepted' science. The first batch of EFSA opinions was published at the end of October 2009, a second batch in February 2010 and a further four batches are expected by December 2011. Over 300 claims were referred back to the EC because they were considered to be either product-specific claims that do not fall under this Article or comparative claims that required further information as to the comparator. The first batch comprised over 500 opinions, of which 30% were positive (mainly in relation to vitamins and minerals), 60% were negative and the remainder were judged to be ambiguous. Failure to reach a positive opinion can be for several reasons: the evidence is insufficient to establish a cause and effect relationship between the consumption of the food/constituent and the claimed effect, for the type of claim being assessed, that is, evidence exists but it is inconclusive; or the evidence to support the claim is, at most, limited and hence the relationship is not established. For Article 13.1 claims, it appears that some of the applications have not provided sufficient characterisation of the food/ingredient, for example, the strain of probiotic to which the proposed health benefit related, and in a number of cases the application should have been made under Article 13.5 or 14 via a comprehensive dossier because of the nature of the evidence or of the claim. The Commission has indicated that it expects the first list of permitted article 13.1 health claims to be published in October 2010, and that it intends to introduce a 6-month transition period for all Article 13 claims.

It has become apparent that the characterisation of the food/constituent in question is very important in the approval process. Claims cannot be substantiated if the food/constituent is characterised solely on the basis of the claimed effect, for example, 'non-cariogenic', 'low glycaemic index' and 'antioxidant'. However, EFSA's Panel has indicated that it can assess the effect of a food characterised by its effect on, for example, blood glucose, and then decide whether the effect is beneficial to the proposed target group. If the constituent of interest is recognised to be an essential nutrient, it is more likely to be found to be relevant to Article 13.1 (that is, those based on generally accepted science), even if relatively little is known about its precise function, provided the other conditions are met with respect to the type of evidence available.

Issues and concerns

There still remain a number of inconsistencies and questions in relation to the Regulation, and some of these are under consideration by the Commission and Member States. There is a lack of consistency between the European Regulation and Codex Alimentarius: to make a 'reduced' or 'increased' claim under the Regulation, there has to be a reduction or increase of at least 30%, whereas Codex applies a figure of 25%. Furthermore, the Regulation does not allow claims for smaller reductions, for example, a 10% reduction in salt or fat, and this does not support the stepwise reduction in these nutrients that has been shown in the United Kingdom to be an effective means of reformulation of products by the food industry as it allows consumers to become accustomed gradually to the changes. Discussions are underway regarding whether the Regulation could be amended to make it consistent with Codex and to be more supportive of efforts to reformulate products to make them more healthy, such as allowing nutrition claims to be made where there has been a reduction of at least 10% (for example, in salt or saturated fatty acids) and enabling 'temporary' claims (such as 'now contains 50% less saturated fat') to be made following replacement of a product by a healthier alternative. The Regulation does not currently provide an option to claim 'no added sugar' or 'no added salt/sodium', and this is also under discussion.

Another inconsistency concerns 'source' claims for vitamins and minerals; Codex uses 7.5% of the RDA for liquids (instead of the 15% used in the Regulation for both solids and liquids) and also allows 5% RDA per 100 kcal.

As indicated above, a number of key steps in the enactment of the Regulation are behind schedule, in particular the finalisation of the nutrient profiling procedures and the assessment of claims applications. This is due in large measure to the complexity of the decisions required and the immense interest in the opportunities afforded by this Regulation.

Conclusions

In conclusion, nutrition and health claims is a very topical policy area in which there is an important place for reliable

and high-quality food composition data. The EuroFIR network has assisted EFSA is progressing its work in this very challenging arena, in particular that related to nutrient profiling, and is well placed to continue this role.

Conflict of interest

The authors declare no conflict of interest.

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