

NUTRITION AND HEALTH CLAIMS: LATEST DEVELOPMENT



Michèle Sadler
Consultant
Nutritionist

The European Regulation on nutrition and health claims ((EC) 1924/2006) has been in force for approximately five years (1). The aims are to provide a high degree of consumer protection and to harmonise claims across European Member States. The Regulation provides for a number of developments to be agreed over time, such as the list of well-established health claims and nutrient profiles; however, this is proving to be a very gradual process. To keep patients informed about food claims, it is timely to consider the latest developments in the implementation of this Regulation.

LIST OF AUTHORISED GENERAL FUNCTION HEALTH CLAIMS

The most recent development has been the publication of the authorised 'general function' health claims (Article 13.1), covering all claims except disease risk reduction claims and claims referring to children's development and health (Article 14 claims). The Regulation (EU 432/2012) establishing the list of permitted health claims was published on 25 May 2012 (2) and will apply from 14th December 2012. The permitted claims are listed in the EU register of nutrition and health claims made on foods published on the Commission website (<http://ec.europa.eu/nuhclaims>).

The flexibility of wording of the claims is another challenge, particularly considering the overall European market, as the claims will be used across 27 Member States in multiple languages.

The permitted list consists of 222 specific health claims for substances such as vitamins, minerals, certain fatty acids (e.g. oleic acid, linoleic acid), certain sources of dietary fibre (e.g. barley and oat grain fibre, guar gum), 'sports drinks' (carbohydrate-electrolyte solutions), creatine, foods with a low or reduced content of saturated fatty acids or sodium, lactase enzyme, meal replacements for weight control, olive oil polyphenols, plant sterols and stanols, sugar replacers, sugar-free chewing gum and water (from all sources). Each claim has specific conditions of use and an approved wording. Table 1 shows some examples. Terms and conditions for using the claims have also been published alongside the list of claims (Table 2).

The Regulation establishing the list (2) makes it clear that permitting a claim for a substance does not constitute authorisation to marketing the substance, if this is governed by other legislation (pg 2, w/as 17). Hence some of these substances with permitted claims may have further challenges (3), as some are authorised as food additives, some are not yet authorised

for use in food and in certain Member States some are classified as medicinal.

The flexibility of wording of the claims is another challenge, particularly considering the overall European market, as the claims will be used across 27 Member States in multiple languages.

NON-AUTHORISED HEALTH CLAIMS

Since Regulation 1924/2006 is based on the premise that claims must have prior approval, establishment of the permitted list means in practice that other claims are no longer allowed. A transition period of six months is in operation to allow industry time to remove the approximately 1,600 unauthorised claims from labels, websites, advertising and other commercial communications, to which the Regulation applies. The unauthorised claims have also been published on the Commission website as part of the register, with an explanation as to why they are not permitted. Reasons include no substantiation of cause and effect, the food constituent is not sufficiently characterised, the claim is medicinal, or the claim is not for a beneficial physiological effect or is general and non-specific. In a couple of cases non-authorised claims were scientifically valid (specific claims for sodium and fat), but they were considered to contradict advice to reduce intake of these substances and could thus be confusing to consumers.

PENDING HEALTH CLAIMS

A number of health claims are still pending a decision. These claims can continue to be used and are not subject to the transition period for removal. This includes claims that require further consideration by Member States, claims that were eligible to submit new data for a further assessment by EFSA (i.e. previously judged to be based on insufficient evidence and claims for insufficiently characterised probiotics), and 'beauty claims'. However, by far the most claims on this list are for botanical substances and further consideration is needed to decide how these claims and substances should be regulated, as there are many related issues that are not harmonised across Member States.

ARTICLE 14/13.5 CLAIMS

The Community Register of Claims also includes authorised Article 13.5 and Article 14 claims, i.e. claims based on new and emerging science or that have requested the protection of proprietary data (13.5),

Michèle works with clients in the food and supplements industry and is an expert in nutrition and health claims, including current regulatory developments. Michèle also works with companies to develop appropriate claims and writes scientific dossiers, undertakes systematic reviews and advises on research requirements to support health claims.

Table 1: Examples of authorised Article 13 health claims

Type of Substance	Substance	Claim	Conditions of Use
Food	Meat or fish	Meat or fish contributes to the improvement of iron absorption when eaten with other foods containing iron	Food must contain at least 50g of meat or fish per portion, with information to the consumer that the beneficial effect is obtained by consuming 50g of meat or fish together with food(s) containing non-haem iron.
Food	Foods with a low or reduced content of saturated fatty acids	Reducing consumption of saturated fat contributes to the maintenance of normal blood cholesterol levels	Food to meet criteria for nutrition claims 'low saturated fat' or 'reduced [name of nutrient]'
Nutrient	Vitamin C	Vitamin C contributes to the protection of cells from oxidative stress	Food to meet criteria for a nutrition claim for 'source' of vitamin C
Nutrient	Calcium	Calcium is needed for the maintenance of normal bones	Food to meet criteria for a nutrition claim for 'source' of calcium
Food ingredient	Wheat bran fibre	Wheat bran fibre contributes to an acceleration of intestinal transit	Food to meet criteria for a nutrition claim for 'high fibre', with information to the consumer that the claimed effect is obtained with a daily intake of at least 10g of wheat bran fibre.
Food ingredient	Chitosan	Chitosan contributes to the maintenance of normal blood cholesterol levels	Daily intake of 3.0g of chitosan. Information to the consumer that the beneficial effect is obtained with a daily intake of 3.0g of chitosan

and disease risk reduction claims (14.1a claims) and claims relating to children’s development and health (14.1b) claims. To date, seven disease risk reduction claims, eleven children’s claims and just one Article 13.5 claim have been fully authorised. A number of applications for art 14 and 13.5 claims have received positive opinions, but full authorisation is still awaited. These include a positive opinion for calcium alone or calcium and vitamin D, and reduced loss of bone mineral in post-menopausal women, a risk factor in the development of osteoporotic bone fractures (4). The proposed conditions of use are a daily intake of 1,200mg of calcium from all sources alone or together with 800IU Vitamin D (5). This claim has not yet been authorised as a further opinion is awaited from EFSA regarding upper safe levels of calcium and vitamin D.

NUTRITION CLAIMS

Permitted nutrition claims and their conditions of use were published as an Annex to the Regulation (1), which includes claims such as ‘high fibre’, ‘fat-free’ and ‘energy-reduced’. Since then five additional claims relating to unsaturated fatty acids have been added (6). However, the European Parliament earlier this year rejected a proposal to introduce two new claims (‘No added sodium/salt’, and ‘Now contains X% less [energy, fat, saturated fat, sodium/salt and/or sugars], X being at least 15 percent following reformulation), and to revise the conditions of use for the existing claim ‘Reduced [Name of nutrient]’ in relation to saturated fat and sugars. A new proposal is expected shortly, omitting the reformulation claim as this proved to be controversial.

NUTRIENT PROFILES

A key aspect for the use for nutrition and health claims will be nutrient profiles. Foods and food products must comply with criteria for the content of nutrients, such as fat, saturated fat, trans fatty acids, salt/sodium or possibly sugars in order to bear claims. A first attempt to develop these criteria eventually stalled, a key issue being the high number of exemptions being proposed. Now that progress has been achieved with the list of permitted health claims, nutrient profiles are expected back on the agenda in 2012. Once nutrient profiles are agreed, there will be a 24-month transition period for products to comply.

CONCLUSIONS

The nutrition and health claims Regulation is proving to be highly complex and progress with its implementation is very gradual. The permitted list of ‘general function’ claims is now established, with other claims still to be considered. Progress on adding new nutrition claims is also very slow. Discussions are expected to start again on nutrient profiles during 2012.

Table 2: Terms and Conditions for the EU register of nutrition and health claims

<ul style="list-style-type: none"> Any food business operator can use authorised health claims if conditions of use and any applicable restrictions are respected.
<ul style="list-style-type: none"> Non-authorised health claims should not be used.
<ul style="list-style-type: none"> National authorities control the use of claims.
<ul style="list-style-type: none"> Health claims should only be made for the nutrient, substance, food or food category for which they have been authorised, and not for the food product that contains them.
<ul style="list-style-type: none"> Some flexibility of wording of the claim is possible provided its aim is to help consumer understanding taking into account factors such as linguistic and cultural variations and the target population. Adapted wording must have the same meaning for the consumer as the authorised claim in the EU Register.

References

- Official Journal of the European Union 30.12.2006 Regulation EC 1924/2006 on nutrition and health claims made on foods, and 18.1.2007 Corrigendum to Regulation EC 1924/2006 on nutrition and health claims made on foods
- Official Journal of the European Union 25.5.2012 Commission Regulation 432/2012 Establishing a list of permitted health claims made on foods other than those referring to reduction of disease risk and to children’s development and health
- Sadler MJ (Ed). Foods, nutrients and food ingredients with authorised EU health claims. Woodhead Publishing; In Press
- EFSA. Scientific opinion Calcium + vitamin D2 chewing tablets and bone loss. EFSA Journal 2009, 1180: 1-13
- EFSA. Scientific opinion in relation to the authorisation procedure for health claims on calcium and vitamin D and the reduction of the risk of osteoporotic fracture by reducing bone loss. EFSA Journal 2010, 8(5): 1609
- Official Journal of the European Union 12.2.2010 Amending regulation 1924/2006 with regard to the list of nutrition claims