



BULLETIN INTENDED FOR INTERESTED PARTIES

Update from the European Commission's Working Group meeting on health claims, 31 March 2015

There was discussion on a generic descriptor application and a number of health claims, including those mentioned below.

1. Discussion on a draft Commission Regulation authorising a health claim related to Monacolin K and maintenance of normal blood LDL-cholesterol concentrations and amending Commission Regulation (EU) No 432/2012 (EFSA opinion Q-2012-00736). The document is attached to this update.

An Article 13.5 health claim "Monacolin K from red yeast rice contributes to the maintenance of normal blood cholesterol concentrations" received a positive EFSA opinion. Member States (MS) raised safety concerns about the consumption of Monacolin K by certain groups of the population. The options below were proposed by way of adding safety warnings to the conditions of use (COU). The safety warnings would be a draft amendment to the similar authorised 13.1 general function health claim related to Monacolin K from red yeast rice and maintenance of normal blood cholesterol concentrations listed in Regulation 432/2012.

Option 1: The claim may be used only for foods targeting adults in the general population, except for pregnant and lactating women, wishing to reduce their blood cholesterol concentrations.

Option 2: Foods bearing this health claim must include the following statements:

- A. a statement that the product is not intended for people who do not need to control their blood cholesterol level
- B. a statement that patients on cholesterol lowering medication should only consume the product under medical supervision
- C. an easily visible statement that the food is restricted to adults and is not appropriate for pregnant or breastfeeding women and statin-intolerant people.

We would welcome your written comments on the above options by **1st May 2015** (nutritionlegislation@dh.gsi.gov.uk). Please justify your preferred option.

2. Discussion on a draft Commission Regulation authorising a health claim made on foods and referring to the reduction of disease risk, related to Monacolin K and maintenance of normal blood LDL-cholesterol concentrations (EFSA opinions Q-2012-00968). Article 14(1)(a) claim. Document is attached to this update.

“A combination of artichoke leaf dry extract standardised in caffeoylquinic acids, Monacolin K in red yeast rice, sugar-cane derived policosanols, OPC from French maritime pine bark, garlic dry extract standardised in allicin, d- α -tocopheryl hydrogen succinate, riboflavin and inositol hexanicotinate reduces blood LDL-cholesterol concentrations. High LDL-cholesterol is a risk factor in the development of coronary heart disease”.

This claim received a positive EFSA opinion. Member States had concerns regarding the safety of Monacolin K in red yeast rice. It was noted that the dosage of Monacolin K is lower (i.e. 2mg) of the Article 14(1)(a) health claim (EFSA opinions Q-2012-00968) than the Article 13.5 health claim (EFSA opinion Q-2012-00736) (i.e. 10mg) and if safety warnings were appropriate as discussed in paragraph (1) above then these should be proportionate. It was suggested that the wording referring to food in the COU should specifically refer to food supplements.

MS questioned the number of negative EFSA opinions relating to the substances in the claim, EFSA explained that individually the substances did not elicit an effect but together, as described in this health claim, an effect was observed.

3. Discussion on draft Commission Regulation authorising certain health claims related to non-fermentable carbohydrates and maintenance of tooth mineralisation by decreasing tooth demineralisation (EFSA opinion Q-2013-00040); and to non-digestible carbohydrates and a reduction of post-prandial glycaemic responses (EFSA opinions Q-2013-00615, Q-2014-00073 Q-2014-00044)

The health claims relating to non-fermentable carbohydrates (sugar replacers) and non-digestible carbohydrates (fibre) had minor changes to the previous draft regulation, most notably the addition of wording “and other non-fermentable carbohydrates” to expand the scope. The health claims are “*Consumption of foods/drinks containing <name of all sugar replacers> instead of sugars or other fermentable carbohydrates contributes to the maintenance of tooth mineralisation*” and “*Consumption of foods/drinks containing <name of all sugar replacers> instead of sugars induces a lower blood glucose rise after their consumption compared to sugar-containing foods/drinks*”. It was suggested that rather than listing the substances the text could be “all used sugar replacers”; the Commission agreed to consider this. The draft regulation will be presented for an opinion at the next PAFF Committee meeting in June 2015.

4. Discussion on a draft Commission Regulation refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health (EFSA opinions Q-2013-00974, Q-2014-00127, Q-2014-00126, Q-2014-00153)

The following health claims received EFSA negative opinions as a cause and effect relationship had not been established between the consumption of the food constituent and the effect, and the Commission proposed refusing authorisation:

- Standardised aqueous extract from white kidney bean (*Phaseolus vulgaris* L.) helps to reduce body weight
- Beta-alanine and increase in physical performance during short-duration, high-intensity exercise
- Fat-free yogurts and fermented milks with live yogurt cultures, with added vitamin D, and with no added sugars, help to reduce body and visceral fat in the context of an energy restricted diet
- Fat-free yogurts and fermented milks with live yogurt cultures, with added vitamin D, and with no added sugars, help to maintain lean body mass (muscle and bone) in the context of an energy-restricted diet
- Teestar™ lowers blood glucose levels

There were no comments from MS.

5. Discussion on a draft Commission Regulation authorising a health claim related to “native chicory inulin” and maintenance of normal defecation by increasing stool frequency (EFSA opinion Q-2014-00403)

The Commission explained that there was a positive EFSA opinion for the claimed effect that “Chicory inulin contributes to maintenance of normal defecation by increasing stool frequency”. In considering flexibility of wording of the health claim and consumer friendly language, the claim proposed in the draft regulation is “*Chicory inulin contributes to normal bowel function by increasing stool frequency*”. There were no comments from MS.

6. New Article 13.5 claims – Presentation of new EFSA opinions: Q-2014-00554, Q-2014-00556, Q-2014-00557, Q-2014-00555

For the health claim related to glycaemic carbohydrates and maintenance of normal brain function which received a positive EFSA opinion, the Commission advised that a previous authorisation exists which covers the new claim so a decision is not required and the applicant will be informed.

The health claim relating to glycaemic carbohydrates and contribution to normal cognitive function also received a positive EFSA opinion. The COU proposed by EFSA suggests a daily intake of 130 g of glycaemic carbohydrates to cover the glucose requirement of the brain and such amounts can be consumed as part of a balanced diet; the target population is the general population. There was concern amongst MS about how these claims might be used and the impact on consumers. In particular the health claims may encourage over consumption of

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carbohydrate (particularly sugars) by the general population, conveying a conflicting and confusing public health message to consumers. It was suggested that more restrictions on the COU were needed in line with the approach taken for health claims relating to complex carbohydrates.

7. Discussion on a draft Commission Regulation refusing to authorise a health claim made on foods and referring to the reduction of disease risk, related to L-tug lycopene and reduction of blood LDL-cholesterol (EFSA opinion Q-2014-00590) – SANTE/104497/2015

The Article 14.1(a) health claim referring to a reduction of a disease risk "*L-tug lycopene has been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease*" received an EFSA negative opinion as a cause and effect relationship had not been established between the consumption of the food constituent and the effect. The Commission proposed refusing authorisation; there were no comments from MS.

8. Discussion on a draft Commission Regulation authorising a health claim made on foods and referring to children's development and health, related to ALA and contribution to brain development (EFSA opinion Q-2008-666)

The claim "*Alpha-linolenic acid contributes to brain development*" received an EFSA positive opinion. MS asked what type of foods would be fortified with ALA using this health claim and raised concerns about the impact on children in the absence of nutrient profiles. MS questioned whether this health claim is helpful to consumers given that EFSA considered that the evidence provided does not establish a benefit for brain development in children of ALA intake greater than about 0.2% of total energy and this quantity is consumed as part of a balanced diet.

In relation to the 2g reference daily intake of ALA, it was suggested including in the COU a set limit (e.g. 15%) of the reference value. The Commission suggested that it shall consider this as well as whether the health claim can be expanded to a target population above six years.

9. Application for the term 'probiotico' to be used as generic descriptor in Italy (Art. 1(4) of Regulation (EC) No 1924/2006)

The Commission referred to the application from the Italian authorities for the term '*probiotico*' to be used as a generic descriptor in Italy and the responses from Italy to the specific questions asked following the discussion at the last WG meeting (19th January) where the view was that a health claim and a generic descriptor for the term "probiotico" cannot coexist.

The Italian authority gave an overview of the application and said that the term 'probiotico' had been in use for more than 30 years in Italy.

A number of questions were raised by MS:

-Does the term "probiotico" as a generic descriptor contradict the Commission guidance on the use of the term "probiotic"? It was suggested that "Probiotico" was not considered to be a

generic descriptor as it is a health claim, in accordance with the Commission guidance on the use of the term "probiotic".

- Would the generic descriptor "probiotico" only be valid on products in Italy? The Commission clarified that the derogation would be valid only in Italy and products with "probiotico" on the label would not be permitted in other MS.

-How do consumers in Italy currently interpret the meaning of "probiotico" and "probiotico yogurt?" It was suggested that if consumers currently see a link between "probiotico" / "probiotico yogurt" and a health effect then there are strong reservations on how relevant the term is as a generic descriptor. In response to a question from the Commission on how important a factor consumer understanding is to the designation of "probiotico" as a generic descriptor, a number of MS considered it vital.

In terms of alternatives to a generic descriptor application, MSs had previously debated the term probiotic as a nutrition claim, perhaps using the term as an ingredient e.g. "contains probiotic", but this was dismissed on the basis that probiotic is considered a health claim and not a nutrition claim.

Other claims issues which could be of interest to you:

10. Exchange of views on the use of the statement "suitable for diabetics"

You may wish to be aware of the information provided in the European Commission Summary Report of the Standing Committee on Plants, Animals and Feed, item A.01, relating to an exchange of views on the use of statements such as "Suitable for diabetics" made on foods: http://ec.europa.eu/food/committees/regulatory/scfcah/general_food/index_en.htm).

In the UK, Government advice is that people with diabetes should manage their condition by consuming a healthy balanced diet and that specialist foods are not necessary. This view is supported by Diabetes UK and by NICE guidance to health care professionals which is to "emphasise advice on healthy balanced eating that is applicable to the general population when providing advice to people with type 2 diabetes". The UK Government advice is in line with the European Commission report (2008) on foods for persons suffering from carbohydrate metabolism disorders which stated that specialised foods for diabetics are not necessary [COM \(2008\) 392](#). Regulation (EU) No. 609/2013 on Foods for Specific Groups confirms that there will be no specific category of dietetic products that may make claims of their suitability for diabetics and the statement from the Standing Committee on Plants, Animals and Feed clarifies implementation of the legislation.

Taking account of the EU Standing Committee consensus on the issue as outlined in the Summary Report, the UK Government advice is that statements such as "Diabetic" or "Suitable for diabetics" are not acceptable on foods and we are drawing this to the attention of enforcement officers and to businesses to ensure that that the labelling on these foods is compatible with EU law. Concerned businesses may explore the use of authorised health and nutrition claims for these products instead of the suitable for diabetic's statements.

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At the Standing Committee on Plants, Animals and Feed held on 10 February 2015, one of the European Member States asked whether the use of statements and the marketing of 'foods for diabetics' would be compatible with EU law. These statements such as "Diabetic" or "Suitable for diabetics" are found in particular on some preserves such as marmalades and jams, and can also be found on some confectionary, ice-creams, etc.

The European Commission referred to its *Report on foods for persons suffering from carbohydrate metabolism disorders (diabetes)* [COM \(2008\) 392](#) with the outcome that specialised foods for diabetics are not necessary. The UK agrees with this view and Government advice has been that people with diabetes should manage their condition by consuming a healthy balanced diet and that specialist foods are not necessary. Diabetes UK previously published a position statement (2013) which recommends that manufacturers discontinue the labelling of foods as "Diabetic" or "Suitable for diabetics" which can be found on the following link:

<http://www.diabetes.org.uk/Documents/Position%20statements/Diabetes-UK-position-statement-Diabetic-foods-0213.pdf>.

The European Commission's *Report on foods for persons suffering from carbohydrate metabolism disorders (diabetes)* resulted in the European Commission, the European Parliament and Member States agreeing not to develop further rules for diabetic foods under Directive 2009/39/EC on foodstuffs intended for particular nutritional uses (Parnuts legislation). Regulation (EU) No. 609/2013 on Foods for Specific Groups confirms that there will be no specific category of dietetic products that may make claims of their suitability for diabetics. MS asked the Standing Committee for clarity on whether this outcome provided sufficient legislative powers to remove diabetic products from the market. MS asked this because of the view that, until Regulation (EU) No. 609/2013 on Foods for Specific Groups comes into force (20 July 2016) and the Parnuts provisions are still valid, foods already on the market labelled suitable for diabetics might have this legislative base (and after 20 July 2016 these products should be regulated under general food law, including that on general labelling and nutrition and health claims). The Committee agreed that statements such as "*suitable for diabetics*" should not be considered as health claims (and so could not make an application under Regulation 1924/2006 on nutrition and health claims made of food), but should be evaluated in line with the legal provisions which prohibit misleading food information i.e. Article 7(1) of Regulation (EU) No 1169/2011 on the provision of food information to consumers, or unfair commercial practices (Directive 2005/29/EC). Taking account of the scientific consensus on the matter, the Committee agreed that it would be difficult to consider these statements as compatible with EU law.

Outcome

In relation to the Standing Committee's view that use of these statements should be evaluated in line with Article 7(1) of Regulation (EU) No 1169/2011 on the provision of food information to consumers, our view is that that use of statements such as "Diabetic" or "Suitable for diabetics" is misleading if all similar foods (e.g. foods bearing authorised nutrition claims for reduced

sugar) are suitable for diabetics i.e. Article 7(1) (c) of Regulation (EU) No 1169/2011¹. As such, manufacturers will need to change their labels where they bear these statements and it will be for the Home/Primary Authority to liaise with the business to assist with compliance in the first instance.

Prepared by Nutrition Legislation Team, Obesity & Food Policy Branch, Health & Wellbeing Division

Article 7

Fair information practices

1. Food information shall not be misleading, particularly:

(a) as to the characteristics of the food and, in particular, as to its nature, identity, properties, composition, quantity, durability, country of origin or place of provenance, method of manufacture or production;

(b) by attributing to the food effects or properties which it does not possess;

(c) by suggesting that the food possesses special characteristics when in fact all similar foods possess such characteristics, in particular by specifically emphasising the presence or absence of certain ingredients and/or nutrients;

(d) by suggesting, by means of the appearance, the description or pictorial representations, the presence of a particular food or an ingredient, while in reality a component naturally present or an ingredient normally used in that food has been substituted with a different component or a different ingredient.

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