BULLETIN INTENDED FOR INTERESTED PARTIES

Update from the European Commission’s Working Group meeting on health claims, 20th June 2016

There was discussion on a number of health claims, and an update on the caffeine claims and on the use of the term “Probiotic” on foods. Your views are invited in relation to items 6 and 7 in particular.

1. Discussion on a health claim on Water-Soluble Tomato Concentrate (WSTC) I and II and normal platelet aggregation Article 13(5) of Regulation (EC) No 1924/2006

The draft Regulation effectively converts the protected health claim relating to Water-Soluble Tomato Concentrate (known as FruitFlow) to an unprotected one that any food business can use (provided their product meets the conditions of use).

The draft Regulation is open for comment until 5 July and will then be presented for an opinion at EU Standing Committee on Plants, Animals, Food and Feed under the Article 18.4 procedure by consultation.

2. Discussion on a health claim related to glycaemic carbohydrates and cognitive function Article 13(5) of Regulation (EC) No 1924/2006

Reference was made to a recent EU General Court case brought about by Dextro Energy. The EGC ruling found that the Commission did not err in rejecting a number of health claims relating to glucose and energy metabolism on the basis that they encouraged the consumption of sugar, which is incompatible with generally accepted principles of nutrition and health. The ruling means that a number of health claims relating to glucose cannot be authorised. In light of the ruling it was proposed that the health claim relating to carbohydrates and cognitive function should be rejected (as the claim could not be used on glucose it would be unfair to the applicant if it was authorised for use on non-glucose carbohydrates).

The health claim will be presented for an opinion at Standing Committee under the Article 18.4 procedure by consultation.

The wording of the health claim has been revised in the latest draft Regulation to “Lactitol contributes to normal bowel function by increasing stool frequency”. The conditions of use were revised to: “The claim may be used only for food which contains 10g of lactitol in a single quantified portion. In order to bear the claim, information shall be given to the consumer that the beneficial effect is obtained by consuming 10g of lactitol daily and that the daily dose of 10g lactitol should not be exceeded. Information shall also be given to the consumer that the excessive consumption of lactitol may produce laxative effects”.

Some Member States raised concerns regarding the safety of lactitol and were advised to direct their concerns to the Working Group on Novel Foods, as it was currently considering an application for lactitol as a food ingredient. The discussions at the Working Group on Novel Foods would inform further discussion/a decision on the health claim.


EFSA gave a positive opinion on the health claim. A few Member States raised concerns about the highly technical conditions of use and whether consumers would understand the meaning of resistance training being performed at an intensity of at least 65%-75% of one repetition maximum. One Member State suggested that a footnote explaining that “repetition maximum is the maximum weight or force an individual can exert in a single lift” could be helpful.

The health claim will be presented for an opinion at Standing Committee under the Article 18.4 procedure by consultation.

5. Discussion on a draft Commission Regulation refusing to authorise certain health claims made on foods related to Fabenol® Max and reduction of the absorption of carbohydrates, to DHA and improvement of memory function, and to polydextrose and maintenance of normal defecation Article 13(5) of Regulation (EC) No 1924/2006

The three health claims received negative opinions from EFSA as a cause and effect relationship had not been established between the consumption of the food constituent and the effect.

In relation to the polydextrose and maintenance of normal defecation claim, one Member State indicated that it is investigating an issue raised by the applicant regarding the EFSA application/assessment process and requested a delay from the Commission in seeking agreement to reject. The draft Regulation is open for comment until 24 June.
6. 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 Article 14(1)(a) of Regulation (EC) No 1924/2006

Regarding the health claim relating to a high intake of Monacolin K claim (10mg), a procedural issue\(^1\) in relation to adoption would prevent the replacement of the authorised health claim with a new entry, revised to include additional warning statements in the conditions of use. The Commission therefore proposed launching Article 8 of Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods, and thereby requested EFSA to make an assessment of the safety of Monacolin K.

The intention is to proceed with the health claim relating to the lower 2mg concentration of Monacolin K. A few Member States raised concerns that the latest draft of the Regulation had the warning statements removed. In order to come to an informed view on the need for safety warnings on the health claim, Member States were asked to submit information on the use of safety warnings on Monacolin K food supplements on their market. If you are able to provide information to assist the UK with this submission, please email your information to our mailbox nutritionlegislation@dh.gsi.gov.uk by 20 July.

7. Exchange of views with Member States on health claim made on foods and referring to children's development and health – Follow-up discussion on point B.06 of the agenda of Standing Committee meeting of 12 April 2016 Article 14(1)(b) of Regulation (EC) No 1924/2006

There was discussion on what constitutes the age group “children” in light of the approval at the PAFF Committee held on 12 April 2016 to authorise the health claim for “Vitamin D contributes to the normal function of the immune system in children” where the targeted age group is children from 3 to 18 years of age.

There was discussion on the twenty health claims targeted at children, which received positive opinions from EFSA, but have been pending due to developments relating to Regulation 609/2013 on Foods for Specific Groups (FSG) and the Delegated Act on Infant formulae and follow-on formulae which has now been adopted. A decision would have to be made on how to deal with the health claims, but there were some reservations regarding the potential for the claims to be used on follow-on formulae.

The Commission will send Member States a list of questions covering the different categories of food (e.g. follow-on formulae, baby foods) in order to seek views on how to treat health claims for these food categories. We will forward the questions to stakeholders when available, and your views will be requested in order to inform the UK position.

\(^1\) The authorised health claim relating to Monacolin K was previously adopted by vote and the same procedure would need to be followed for the amendment, but this was not possible as the consultation procedure would apply
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Update of Caffeine claims

The European Parliament (EP) lodged an objection to the caffeine claims which received a favourable opinion by qualified majority vote at Standing Committee on 12 April. The objection was upheld and will be voted on at EP Plenary in early July. The EP objection\(^2\) is on the grounds that sugary drinks and energy drinks containing caffeine should not display claims that they can help increase alertness or concentration, as this would encourage high consumption of sugar among adolescents, who are the largest group of energy drink consumers.

Update on use of the term “Probiotic”

The Commission is considering the option of using the term “Probiotic” as a voluntary statement under Regulation 1169/2011 on the provision of food information to consumers, although this is not a fixed position. There is an indication of commitment to resolve the issue.

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\(^2\) The EP objection is on the grounds that the health claims on caffeine are not compatible with the aims of the legislation as:

a) According to the draft measure, the claims on alertness and concentration shall not be used on food targeting children, including adolescents. However, adolescents represent the biggest group of consumers of energy drinks.

b) While the Commission has still not set nutrient profiles, as required under the Health Claims Regulation, the health claims on caffeine could be used on energy drinks, which have a high sugar content.