Department of Health

BULLETIN INTENDED FOR INTERESTED PARTIES

Update from the European Commission's Working Group meeting on health claims, 16 May 2014

At this meeting we discussed a large number of health claims, including those mentioned below.

1. **Discussion on a draft Commission Regulation on the authorisation of health claim related to glycaemic carbohydrates and recovery of normal muscle function (contraction) after strenuous exercise (Q-2013-00234):** The Commission presented a draft regulation to Member States (MS) by indicating that the COU (conditions of use) included the definition of strenuous exercise, the amount of carbohydrate needed to obtain the beneficial effect and frequency of consumption. It was suggested possibly to define glycaemic carbohydrates as in the carbohydrate / brain claim already authorised i.e. "carbohydrates that are metabolised by humans (excluding polyols)".

   However, there is still concern that the claim is not clearly targeted at people having done intensive exercise and that it will encourage over consumption of carbohydrate (particularly sugars) by the general population. A question raised in the working group meeting was: whether the proposed intake of 4g glycaemic carbohydrate per kg body weight could lead to a large consumption of carbohydrate within a short period of time.

2. **Discussion on a health claim related to hydroxyanthracene derivatives (HD) and improvement of bowel function (Q-2013-00650):** Issues to consider for this potential claim are whether it would be considered medicinal and how safety issues should be addressed in the conditions of use. Questions raised at the meeting were:

- What legal basis in the claims legislation there could be for not authorising the claim given that it had received a positive opinion from the European Food Safety Authority (EFSA)?
- Where food supplements containing HD were on the market what are the maximum permitted doses?
- What are consumer perceptions of such products?
- How current label warnings compared with the warnings mentioned by EFSA; and any safety issues?

3. **Discussion on health claims related to "non-fermentable carbohydrates" and maintenance of tooth mineralisation (Q-2013-00040) and for a health claim related**

to "non-digestible" carbohydrates and reduction of post–prandial glycaemic responses (Q-2013-0015): The Commission introduced the draft regulation which would authorise the above claims. The draft proposal includes a definition of non-fermentable carbohydrates and non-digestible carbohydrates.

Question raised in the meeting:

- Referring to the claim about non digestible carbohydrates it would be useful to clarify whether the claim could be used on all dietary fibres. Would it be appropriate to define "dietary fibre" as specified in the Food Information to Consumer Regulation?

4. **Discussion on five health claims related to glucose and energy-yielding metabolism (Q-2012-00266, Q-2012-00267, Q-2012-00268, Q-2012-00269 and Q-2012-00270):** These claims have been discussed several times at previous working group meetings. MS have voiced concerns that the claims could encourage overconsumption of sugar in the general population.

   It was concluded that, although EFSA had published positive opinions on the above five health claims, it could be possible to reject these claims on the basis that the use of these claims would convey a conflicting and confusing message to consumers. The claims would encourage consumption of sugar which, on the basis of generally accepted scientific advice, European, national and international authorities, advise consumers to reduce their intake. Therefore, the five claims above do not comply with point (a) of the second paragraph of Article 3 of Regulation (EC) No 1924/2006 which foresees that the use of claims shall not be ambiguous or misleading.

5. **Discussion on a draft Commission Regulation refusing to authorise health claims for Yestimum® , Transitech®, Bimuno GOS®, Lactobacillus rhamnosus GG (LGG), VeriSol® P and zinc (Q-2012-00761, Q-2013-00087, Q-2012-01007, Q2013-00015, Q-2012-00839, Q-2010-01092) & Discussion on Working Document (SANCO/11586/2013) Statement concerning target populations under medical treatment SCFCAH meeting -13 June 2014:** These claims have been discussed previously at working group meetings. The Commission explained that the reason for rejecting the claim *Lactobacillus rhamnosus GG* (LGG) and maintenance of normal defaecation during antibiotic treatment is because EFSA's opinion on the evidence was not supportive of the claim, rather than because the target population was under medical treatment.

6. **Discussion of a draft Commission Regulation refusing to authorise health claims on Caffeine (Q-2013-00399), Rosbacher drive ® (Q-2013-00444), and Cytidine 5-diphosphocholone (CDP-choline or citicoline) (Q-2013-00757):** There were no comments from MS on these three negative EFSA opinions. It was discussed that the claims will not be authorised.

7. **New Article 14(1)(a) claims-h Discussion on a draft Commission Regulation refusing to authorise health claims on "Beta-palmitate" (Q-2008-174), "Choline" (Q-2008-134), "Complex carbohydrates" (Q-2008-131)**

Choline is needed for the development of brain of infants and young children from birth to three years" (Q-2008-134): EFSA was asked why the opinion on the above claim concluded that the effect "i.e. brain development" is thought to be general and non-specific, and does not refer to any specific health claim. In response, EFSA said choline is not an essential nutrient and there was no evidence to suggest that choline has a specific function in the brain.

There were no comments on the negative EFSA health claim opinions relating to beta-palmitate (Q-2008-174) and complex carbohydrates (Q-2008-131). It was discussed that all three health claims above will be rejected.

8. **Information on the procedures to be followed in view of the expiry date (18/12/2014) of the restriction of use of the claim on Water-Soluble Tomato Concentrate (WSTC) I and II and normal platelet aggregation (EFSA opinions Q-2009-00229, Q-2010-00809):** The health claim "Water-Soluble Tomato Concentrate (WSTC) I and II helps maintain normal platelet aggregation, which contributes to healthy blood flow" was authorised on 17 December 2009. Seven unpublished studies submitted by the applicant in its dossier of evidence in support of the application were considered to meet the requirements of Article 21(1) of Regulation 1924/2006. Therefore, Article 2 of the Commission Decision authorising the claim (OJEU L 336/55 18.12.2009) states that "The scientific data and other information included in the [seven unpublished] studies shall be restricted for use for the benefit of the applicant for a period of 5 years". The claim was subsequently included in a section of the EU Register of health claims entitled "Health claims for which protection of proprietary data has been granted (and for which the right of use of the claim is restricted to the benefit of the applicant)".

   The five year period ends in December 2014 and it would be necessary to draft a new legal act so that the claim could possibly be authorised without restriction of use - as foreseen in Article 18(5) (b) of Regulation 1924/2006.

Next Working Group Meeting:
Provisionally September 2014

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