Department of Health

BULLETIN INTENDED FOR INTERESTED PARTIES

Update from the European Commission's Working Group meeting on health claims, 9th November 2015

There was discussion on a large number of health claims, and on a number of applications for terms as generic descriptors. Your views are invited in relation to items 1, 2 and 4.

1. **Discussion on a draft Commission Regulation authorising certain health claims related to caffeine and amending Commission Regulation (EU) No 432/2012** (EFSA opinion 2011;9(4):2053 and 2011;9(4):2054) – SANTE/12128/2015

A draft Regulation proposing to authorise the following health claims on caffeine was discussed:

- Caffeine contributes to an increase in endurance performance, targeting adults performing endurance exercise
- Caffeine contributes to an increase in endurance capacity, targeting adults performing endurance exercise
- Caffeine helps to increase alertness, targeting the adult population
- Caffeine helps to improve concentration, targeting the adult population.

A fifth health claim on caffeine and reduction in the rated perceived exertion/effort during exercise is proposed for rejection as the conditions of use for the beneficial effect (a caffeine intake of 4mg/kg body weight one hour prior to exercise) exceeds the limit of 3mg/kg body weight recommended by EFSA as a safe caffeine intake.

The draft Regulation includes a safety warning "Information shall also be given to the consumer not to exceed a daily intake of 400mg of caffeine" and it was proposed that the warning should be revised to "Information shall also be given to the consumer that it is recommended not to exceed a daily intake of 400mg of caffeine". An additional safety warning recommending not to exceed an intake of 200mg caffeine in a single dose was proposed by Member States. It was also proposed that the two caffeine claims targeting the adult population (*Caffeine helps to increase alertness* and *Caffeine helps to improve concentration*) should have additional wording in the conditions of use so that it 'shall not be used for claims targeting children'.

If you have any comments on the draft Regulation and the proposed wording of the conditions of use please email your views to nutritionlegislation@dh.gsi.gov.uk by **20 November 2015.**

2. Exchange of views on the adaptations of Regulation (EU) No 432/2012 with respect to health claims on meal replacement for weight control

Regulation 432/2012 authorises the use of two health claims related to meal replacements for weight control. The conditions of use set for these claims refer to Directive 96/8/EC on foods intended for use in energy-restricted diets for weight reduction. However, when Regulation 609/2013 on foods for specific groups enters into application on 20 July 2016, Directive 96/8/EC will be repealed. As a consequence, the conditions of use for the two authorised health claims on meal replacements need to be amended. There are three main changes:

(i) Essential composition, the detail laid out in Directive 96/8/EC will be revised in line with Annex 13 of Regulation 1169/2011, EU FIC (EFSA advised that the claimed effect would remain valid with this approach)

(ii) Energy content, the 200-400 kcal value detailed in Directive 96/8/EC needs revising to take account of the claimed effect relating to a maximum value of 250 kcal. The Commission proposed using the EFSA assessment for the health claim (in order to bear the claim the energy of the food shall not exceed 250kcal) with a 3 year transition time for adoption (coming into force 20 July 2016)

(iii) Food category, this is revised from "Meal replacement for weight control" to "Food presented as replacing one daily meal" to better explain the purpose of the product.

A slight amendment to the wording of the claim was proposed by Member States so that that it is clear that it relates to substituting daily one *main* meal (to avoid consumers snacking on meal replacements).

The Department of Health previously drew to the attention of the Commission that there are differences between the list of permitted vitamins and minerals under Regulation (EC) No 953/2009 (to be repealed when Regulation (EU) No 609/2013 comes into force on 20 July 2016) and Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods. The differences are related to the fact that Regulation (EC) No 953/2009 includes substances which are not permitted under Regulation (EC) No 1925/2006. Calcium and magnesium bisglycinate are currently used in meal replacement products and, unless action is taken, their use will not be permitted after Directive 96/8/EC is repealed. The Commission wrote to all Member States in September to ask them how this will affect products on their markets and received no response. The Commission advised that affected businesses should submit a dossier for use of substances following the procedure set out in Regulation 1925/2006. Businesses would be allowed to use up their stocks and would then need to comply with the rules from 20 July 2016 for new products.

If you have any comments on the draft regulation and in particular the impact of not being able to use certain substances (including calcium and magnesium bisglycinate) in meal replacements after 20 July 2016 please email your views to nutritionlegislation@dh.gsi.gov.uk by **30 November 2015**.

3. **Discussion on a health claim related to glycaemic carbohydrates and cognitive function (EFSA opinion Q-2014-00555) – SANTE/10889/2015**

A health claim relating to glycaemic carbohydrates and contribution to normal cognitive function received a positive opinion, but Member States previously raised concerns about how these claims might be used and the impact on consumers. Member States proposed that the claim in the draft Regulation should be revised to glycaemic carbohydrates contribute to normal cognitive function (i.e. remove the word "maintenance") and the conditions of use for the claim could be extended to carry a statement that "a normal balanced diet will give adequate carbohydrate to support cognitive function".

4. **Discussion on a health claim related hydroxyanthracene derivatives and improvement of bowel function (EFSA opinion Q-2013-00650)** *Article 13(5) of Regulation (EC) No 1924/2006*

This claim, which received a positive EFSA opinion, has already been discussed at three previous Working Group meetings and a number of Member States indicated that they would consider this a medicinal ingredient/claim and expressed concerns about safety. The Commission sent a questionnaire to Member States last year and reported that, of the 18 Member States who replied, 8 considered the substance medicinal, 4 considered it both a medicine and a food supplement, and 9 considered it a food (mainly as a food supplement and some as candy). Six Member States reported the use of warning statements (not for children or pregnant/breast feeding women). Regarding safety concerns, 5 Member States replied and cited advice to follow the safety leaflet, consult a doctor, potential concern if used for weight loss, and limited adverse reports were recorded.

The Commission suggested two solutions:

- Option 1: Do not authorise the health claim
- Option 2: Place the substance under Community scrutiny following the procedure in Regulation 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods (Annex III).

If you have any views on the options regarding the draft regulation please email your views to nutritionlegislation@dh.gsi.gov.uk by **30 November 2015.**

5. **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-2013-00399, Q-2014-00673, Q-2014-00566, Q-2014-00405, Q-2014-00624, Q-2014-00567, Q-2014-00580) – SANTE/12134/2015**

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:

- Caffeine helps to increase alertness
- The consumption of Clarinol® or Tonalin® contributes to a reduction in body fat mass
- SYNBIO® persists in the intestinal tract and favours the natural regularity contributing to maintain and improve human intestinal well-being
- FRUIT UP® reduces post-prandial blood glucose responses compared to high-glycaemic carbohydrates
- A combination of standardised pomegranate pomace extract and greater galangal rhizome powder increases the number of motile spermatozoa in semen
- *Bifidobacterium bifidum* CNCM I-3426 increases the proportion of healthy days by maintaining normal immune function in healthy adults during everyday life events such as moderate stress
- Regular consumption of coffee C21 contributes to the maintenance of DNA integrity in cells of the body.

Regarding the health claim on caffeine, the draft Regulation makes it clear that the rejected claim relates to doses of caffeine between 40 mg per serving and 75 mg per serving so that there is no confusion with the caffeine claim discussed under item 1 (where the conditions of use indicate at least 75 mg caffeine per portion in line with the positive opinion from EFSA).

6. 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 Symbiosal® and lowering of blood pressure (EFSA opinion Q-2014-00366) – SANTE/12136/2015

The health claim "*Symbiosal has been shown to lower the rising of blood pressure when used as a replacement of traditional table salt. The rising of blood pressure is a risk factor for high blood pressure (hypertension)*" 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. There were no comments from Member States and the Commission proposed refusing authorisation.

7. Discussion on a draft Commission Regulation refusing to authorise a health claim made on foods and referring to children's development and health (EFSA opinions: Q-2014-00404) - SANTE/12135/2015

The claim "*Colief®/lactase enzyme reduces the lactose load of the infant's feed and improves the consequences of lactose maldigestion in colicky infants unable to effectively digest all the lactose in their feed*" 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. There were no comments from Member States and the Commission proposed refusing authorisation.

8. Generic Descriptors – Article 1(4) of Regulation (EC) No 1924/2006

Draft Regulations permitting the use of the following terms as generic descriptors were discussed:

- *'tonic'* – application submitted by the UK and will apply to the entire EU, although Recital 11 makes it clear that for some MSs the term (and it linguistic variants) is not considered a health claim and is out of scope of the Regulation (rather than having a derogation as a generic descriptor in those named MSs). There were some amendments proposed to the linguistic variants used in some Member States, but otherwise it will process through the Commission's inter-service processes for a vote at a future Standing Committee

- *'biscotto salute'* - application submitted by Italy and the derogation will apply in Italy and possibly Malta (to be considered further)

- *'Hustenbonbon'* and *'Hustenstopper'* - application submitted by Austria and the derogation will apply to the entire EU but will be effective in Austria and Germany. It was proposed that the term *'Hustenbonbon'* should be a separate Regulation to *'Hustenstopper'* and should have linguistic variants including 'cough drop'

- *'Hustensirup'* and *'Hustenzuckerl'* - application submitted by Austria and the derogation will apply to the entire EU for *'Hustenzuckerl'* and will apply to Austria only for *'Hustensirup'*

- *'Brust-Caramellen', 'Halsbonbon'* and *Keelpastilles'* - application submitted by Germany and the derogation will apply to the entire EU

- '*Hustenperle'* - application submitted by Germany and the derogation will apply to the entire EU

- '*Hustenmischung'* - application submitted by Germany and the derogation will apply to the entire EU

9. Presentation by the Commission of the roadmap on the evaluation of a) Regulation (EC) No 1924/2006 on nutrition and health claims made on food with regard to nutrient profiles and health claims made on plants and their preparations and of b) the general regulatory framework for their use in foods

The Commission presented the roadmap proposal which will focus on evaluating the need for nutrient profiles and the issue of on-hold health claims made on plants/botanicals . The Commission has failed to implement Regulation 1924/2006 with regard to these two issues. The final report will be expected by the end of 2017 and will pave the way for an action plan. The next steps could be a revision of the Regulation, withholding parts of the Regulation, or a new piece of legislation. The review will feed into the wider evaluation of the Regulation in the future. The roadmap can be found on the following link:

http://ec.europa.eu/smart-regulation/roadmaps/docs/2015_sante_595_evaluation_health_claims_en.pdf

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Q1. Member States views were sought on the use of Article 10(3) of the Regulation which allows the use of easy, attractive statements which make reference to general, non-specific benefits of a food for overall good health or health-related well-being, without prior authorisation, subject to specific conditions. Slovenia presented the case of a food supplement on their market which is labelled with the general non-specific health claim “For maintaining a health bladder” and the specific health claim “Biotin and B2 contribute to maintaining normal mucous membranes”. The FBO considered it legal to use the general claim on bladder health because it was supported by a specific authorised claim relating to biotin and vitamin B2 and mucous membrane, but the Competent Authority considered that the use of general non-specific claims in this way could be misleading. Member States and the Commission supported the Competent Authority’s view that this was misleading. The Commission referred to its guidance (Commission Implementing Decision 2013/63/EU, Annex) which states that “the specific claims from the lists of permitted health claims should bear some relevance to the general reference”.

Q2. Member States views were sought regarding the conditions of use of the claim “with no added sugars” and stated that the claim cannot be used for products which contain food used for its sweetening properties. Sweeteners are regarded as food by Regulation 178/2002 and they are used for their sweetening properties. Therefore a strict legal interpretation of the conditions of use prevents products containing sweeteners to use the claim “with no added sugars”. However, this interpretation is contested by some FBOs and the Competent Authority welcomed views from other Member States and the Commission on how the conditions of use should be interpreted. The Commission agreed that the legal interpretation of the conditions of use prevents products containing sweeteners to use the “with no added sugars” health claim.

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