Department of Health

BULLETIN INTENDED FOR INTERESTED PARTIES

Update from the European Commission's Working Group meeting on health claims, 18th February 2016

There was discussion on a number of health claims, on a number of applications for terms as generic descriptors, on the REFIT evaluation, and an AOB item on the use of the term "Probiotic" on foods. Your views are invited in relation to items 3 and 8 in particular.

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

The European Commission previously suggested two solutions to Member States' concerns regarding the safety of the product and the issue of the health claim (1) do not authorise the health claim, although it would be difficult to reject the claim which has a positive EFSA opinion (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). The Commission decided to progress with Option 2. The claim cannot be used during the period of scrutiny (~4 years) effectively placing it "on hold" and it will then be considered for authorisation (or rejection) in light of the EFSA opinion when published at the end of the scrutiny period. The request for information and data to support the scientific assessment on hydroxyanthracene derivatives will be published on the Commission website so that stakeholders are aware and can submit data.

2. **Update on draft Commission Regulation authorising certain health claims related to non-fermentable carbohydrates and maintenance of tooth mineralisation by decreasing tooth demineralisation; and to non-digestible carbohydrates and a reduction of post-prandial glycaemic responses** (EFSA opinions Q-2013-00615, Q-2014-00073, Q-2014-00044) – SANTE/10466/2015 *Article 13(5) of Regulation (EC) No 1924/2006*

The draft Regulation of the tooth mineralisation health claim no longer refers to "sugar replacers" as there are authorised claims for sugar replacers and intense sweeteners and there

is no need to include them again in these health claims. Regarding the claim "*Consumption of foods containing non-digestible carbohydrates instead of sugars induces a lower blood glucose rise after their consumption compared to sugar containing foods*", following a question on fibre it was clarified that not all non-digestible carbohydrates are considered as fibre and it would limit the scope of the health claim to refer to fibre. The two claims will be authorised.

3. **Discussion on a draft Commission Regulation authorising a health claim related to lactitol and maintenance of normal defecation** (EFSA opinion Q-2015-00375) – SANTE/10219/2016 *Article 13(5) of Regulation (EC) No 1924/2006*

EFSA gave a positive opinion on the claim "*Lactitol can contribute to normal defecation*" and one of the Member States asked whether more consumer friendly wording for the claim such as "lactitol contributes to normal bowel function" could be considered. Any alternative wording will need to be considered in light of the science as it needs to be accurate. Some Member States raised concerns regarding the safety of lactitol (a polyol) and suggested more detailed conditions of use and safety warnings may be necessary, such as 'not suitable for children'. Comments are welcome by 28 February.

If you have any comments on the draft Regulation, the wording of the claim and the conditions of use, please email your views to nutritionlegislation@dh.gsi.gov.uk by **28 February 2016.**

4. **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 short-chain fructooligosaccharides from sucrose and maintenance of normal defecation** (EFSA opinion Q-2015-00377) – SANTE/10220/2016
   Article 13(5) of Regulation (EC) No 1924/2006

Although the health claim 'short-chain fructooligosaccharides maintain intestinal regularity' was proposed by the applicant, upon a request from EFSA the applicant confirmed that the claimed effect refers to maintenance of normal defecation. The health claim 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 claim will not be authorised.

5. **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 Anxiofit-1 and reduction of subthreshold and mild anxiety** (EFSA opinion Q-2015-00006) – SANTE/10221/2016
   Article 14(1)(a) of Regulation (EC) No 1924/2006

The health claim 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 claim will not be authorised.

6. **Discussion on a draft Commission Regulation refusing to authorise a health claim made on foods and referring to children's development and health, related to Equazen eye q® and improving reading ability** (EFSA opinions: Q-2014-00462) - SANTE/12498/2015
   Article 14(1)(b) of Regulation (EC) No 1924/2006

The health claim 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 claim will not be authorised.

7. **Discussion on a draft Commission Regulation authorising a health claim made on foods and referring to children's development and health, related to vitamin D and normal function of the immune system** (EFSA opinions: Q-2014-00826) - SANTE/12500/2015
   Article 14(1)(b) of Regulation (EC) No 1924/2006

EFSA previously assessed a claim on vitamin D and contribution to the normal function of the immune system with a favourable opinion (2010) where the target population was the general population. For this claim targeting children, EFSA considered that vitamin D plays a regulatory role in the functioning of the immune system and that the role of vitamin D in the functioning of the immune system applies to all ages, including children. In order to bear the claim, a food should be at least a source of vitamin D as per the Annex to Regulation (EC) No 1924/2006. The target population is children from 3 to 18 years of age and tolerable Upper Intake Levels have been established for vitamin D in this age group, set at 50 µg/day for children aged 1 to 10 years and 100 µg/day for adolescents aged 11 to 17 years (same as for adults). The health claim will be authorised.

8. **Generic Descriptors – Discussion on a draft Commission Regulation concerning the first applications for generic descriptors** *Article 1(4) of Regulation (EC) No 1924/2006*

The draft proposal lists the applications for generic descriptors that Member States consider acceptable to date. Regarding “Tonic” as used for tonic water, there will be some amendments to more accurately reflect the linguistic variations used in all Member States. There were no comments on the generic descriptor “Biscotto salute” for use on rusk-type bakery products. The draft Regulation listing the generic descriptors “Tonic” and “Biscotto salute” will progress to Standing Committee for a vote.

For the applications on “Hustenbonbon”, 'Hustenstopper' 'Hustensirup' and 'Hustenzuckerl', a request was made to include other related applications at the same time for authorisation, which will include “cough drop”. If there are other similar terms that the UK industry would like to use on their products, e.g. “cough candy”, please contact our mailbox nutritionlegislation@dh.gsi.gov.uk **as soon as possible** and we will coordinate with other Member States leading on this application.

9. REFIT 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 provided an update regarding the REFIT proposal which will focus on evaluating the need for nutrient profiles and the issue of on-hold health claims made on plants/botanicals. The list of questions to be investigated by the contractor was considered and Member States were asked to submit any additional questions by the following day.

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

AOB

Q1. With reference to (i) mandatory nutrition labelling under the food information to consumers Regulation (which comes into force December 2016) and (ii) requirements under the EU Directive 2001/113/CE relating to fruit jams, jellies and sweetened chestnut purée, Member States views were sought on whether it will be necessary to provide the total sugar content measured by refractometer in addition to the total sugar content for nutrition labelling, adding that the figures will differ and may be confusing for consumers. It was concluded that both are required under the separate legislation, but, where a nutrition claim is made for sugars, there is an exemption on the need to indicate the sugar value determined by refractometer.

Q2. The use of the term “Probiotic” on foods was discussed and a number of Member States called upon the Commission to set up a sub-group of the working group on health claims to consider options which may provide a solution to the current impasse which is stifling the research, innovation and marketing of probiotic foods in Europe. The Commission had some sympathy with industry regarding the current situation, but would need political clearance on any proposals. The Commission took note of the Member States who supported the initiative and asked for views from others, particularly those who would be unable to support the initiative as it will be critical to have a coherent position to move forward.

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