Department of Health

BULLETIN INTENDED FOR INTERESTED PARTIES

Update from the European Commission's Working Group meeting on health claims, 8th June 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, 3, 7, and 10.

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).
and
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.

Following the last Bulletin of 31 March and our submission of written comments on these health claims, most Members States favoured the use of warning statements on food supplements containing the substance Monacolin K. The Commission proposed taking such food out of the Regulation on health claims and placing under Regulation (EU) No 1169/20112 on the provision of food information to consumers (FIC) alongside foods containing substances with similar safety warnings (phytostanols and phytosterols). An expert group will be convened to amend FIC by a delegated act.

If you have any comments on the proposed approach please email your views to nutritionlegislation@dh.gsi.gov.uk by **20th July 2015.**

3. Discussion on a draft Commission Regulation authorising a health claim related to glycaemic carbohydrates and cognitive function and amending Commission Regulation (EU) No 432/2012 (EFSA opinion Q-2014-00555)

A health claim relating to carbohydrates and contribution to the maintenance of normal cognitive function received a positive opinion, but Member States raised concerns about how these claims might be used and the impact on consumers. Member States also deliberated whether the authorised health claim for "*Carbohydrates contribute to the maintenance of normal brain*

function" captured the new health claim on cognitive function, so that it would be unnecessary to authorise this new claim. We would welcome your views on whether this is an appropriate approach and possible limitations (e.g. if a board health claim on "normal brain function" covers more specific health claims on cogitative function, on memory, etc., on whether this may cause problems with flexibility of wording, and how could this be controlled, etc.).

If you have any comments on whether the "*Carbohydrates contribute to the maintenance of normal brain function*" captures the new cognitive function claim, please email your views to nutritionlegislation@dh.gsi.gov.uk by **20th July 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-2014-00097, Q-2014-00058)

The following Article 13(5) 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:

- ***Lactobacillus plantarum* TENSIA®**: Regular, at least for eight week consumption of 50 g/day *Lactobacillus plantarum* TENSIA comprising Südamejuust (English translation: Heart cheese) of the Harmony brand helps to maintain the cardio-vascular system/heart health through reduction of blood pressure/Symbol of heart/.
- **Carbohydrate solutions**: Contribute to the maintenance of endurance performance during prolonged endurance exercise.

There were limited comments from MS.

5. *Discussion on a draft Commission Regulation refusing to authorise a health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health (EFSA opinions Q-2014-00012)*

For the Article 13(5) health claim **"***high-fibre sourdough rye bread and reduction of post-prandial glycaemic responses compared with glucose*" EFSA concluded a cause and effect relationship had been established between the consumption of the food constituents and the effect, but also concluded that this effect could be established for almost any food compared to glucose. As such, this claim would be considered misleading in accordance with point (c) of paragraph 1 of Article 7 EU FIC which provides that food information shall not be misleading, by suggesting that the food possesses special characteristics when in fact all similar foods possess such characteristics. EFSA also considered that solid foods, including high-fibre sourdough rye bread, are generally not considered as an alternative to glucose solutions and in this context, the COU could not be established for this health claim. The Commission proposed refusing authorisation and there were limited comments from MS.

6. *New Article 13(5) claims – Presentation of new EFSA opinions: Q-2014-00673, Q-2014-00566, Q-2014-00405, Q-2014-00624, Q-2014-00567*

Five new Article 13.5 received EFSA negative opinions as a cause and effect relationship had not been established for health claims relating to Bifidobacterium bifidum CNCM I-3426 and defence against pathogens in the upper respiratory tract, a combination of pomegranate pomace extract and greater galangal rhizome powder and an increase in the number of motile spermatozoa in semen, FRUIT UP® and a reduction of post-prandial blood glucose responses, Coffee C21 and a reduction of DNA damage by decreasing spontaneous DNA strand breaks, SYNBIO® and maintenance of normal defecation.

The period for consultation ends 12th June and if no further comments are received a draft regulation refusing to authorise the claims will be presented at the next Working Group.

7. Discussion on a draft Commission Regulation authorising certain health claim made on foods and referring to children's development and health (EFSA opinions: Q-2009-00455, Q-2008-183, Q-2009-00197, Q-2008-150, Q-2008-160, Q-2008-199, Q-2008-184, Q-2008-186, Q-2008-147, Q-2008-176, Q-2008-144, Q-2008-145, Q-2008-178, Q-2008-189, Q-2008-159, Q-2008-190, Q-2014-00059)

A draft Regulation authorising 17 health claims on different nutrients, mostly vitamins and minerals, and ALA and DHA, was presented. The target population (age group) for each of the claims was discussed and it was noted that where the addition of the nutrient is mandatory the claim should be that all (category of) foods contain the nutrient to be in line with the forthcoming Regulation on foods for specific groups. The COU for a number of the claims include use on foods for special medical purposes (FSMPs) and some Member States queried whether FSMPs should carry health claims as their use would be misleading as consumers of FSMPs are patients suffering from diseases or disorders and therefore not the general population. FSMPs are also used under medical supervision and should not be promoted through the use of health claims targeting consumers. It was noted that in line with the forthcoming Regulation on foods for specific groups (FSGs) and when the delegated act on FSMPs comes into force (in about 4 years' time, exact timing still to be agreed) nutrition and health claims on FSMPs will be prohibited. It is therefore a risk management decision as to whether it is appropriate to allow the health claims on FSMPs as per the draft Regulation and amend in ~4 years (tbc) in line with the FSGs Regulation, or to remove them from the draft Regulation now.

If you have any comments on whether it is appropriate to have nutrition and health claims on FSMPs please email your views to nutritionlegislation@dh.gsi.gov.uk by **20th July 2015.**

Reference was made to the Codex discussions regarding follow-on formula (FoF) up to 2 years age group and that these can be seen as replacement for breast milk; as such some Member States queried whether it was appropriate to have nutrition and health claims on FoF. It was noted that such comments were raised at the Working Group on FSGs where the situation for health claims on FoF is at odds with the International Code on marketing of breast-milk substitutes.

If you have any comments on whether it is appropriate to have nutrition and health claims on FoF please email your views to nutritionlegislation@dh.gsi.gov.uk by **20th July 2015.**

8. *New Article 14(1)(b) claims – Presentation of new EFSA opinions: Q-2014-00826*

Following an EFSA positive opinion for the health claim relating to vitamin D and contribution to the normal function of the immune system, the Commission proposed adding this health claim to the draft regulation authorising the 17 nutrients discussed above.

9. Presentation and exchange of views on EFSA's Scientific Opinion on the safety of caffeine

EFSA presented the conclusions of their Scientific Opinion on the safety of caffeine (published May 2015) and MSs discussed the implications for five health claims on caffeine which received positive opinions from EFSA but were placed on-hold for authorisation pending publication the Scientific Opinion on safety. The Commission indicated that a position will be agreed in the coming months and a draft regulation on the caffeine health claims will be presented by Autumn 2015.

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

There was an exchange of views on the application from the UK for the term "tonic" in the form of tonic water, Indian tonic water or quinine tonic water and the equivalent translations, and Member States are required to provide their opinion to the Commission on the valid application by 18 June. It was previously established at the Working Group that the term “tonic” in the context of the application was not a health claim requiring authorisation under Regulation 1924/2006 on nutrition and health claims made on food. The Commission had now also established that no Member States apply the term as a customary name used to satisfy the legal requirement to provide a mandatory name for the purpose of EU FIC. There remained a mix of views that the term is either within the scope of the Regulation on health claims and should be authorised as a generic descriptor (as there is an implied health benefit for the term “tonic”) or that the term is meaningless as a health claim (for some Member States the term does not translate into anything that could be construed as a health claim) and is therefore out of scope of the Regulation. The Commission queried whether there was a need to look at each language to determine whether the term was in or out of scope of the Regulation, and although this may not be an issue for “tonic water” it could be an issue for other generic descriptors and would impact on the free movement of goods. The Commission concluded that the application for the term "tonic" in the form of tonic water, Indian tonic water or quinine tonic water and the equivalent translations fulfilled the criteria for a generic descriptor and it should be adopted.

The Commission indicated that a legal instrument will be adopted to grant a derogation for generic descriptors and there will be a register of authorised generic descriptors. There will be no need to list non-authorised generic descriptors and applicants will be advised of such decisions by letter from the Member State to whom the application was originally submitted.

Member States discussed other applications for generic descriptors: 'Hustenzuckerl', 'Hustenbonbon' 'Hustenstopper', and 'Hustensirup' (cough sweet / cough drop / cough candy and cough syrup) from Austria and 'biscotti salute' (health biscuit) from Italy. We will circulate these applications to our Interested Parties separately and seek your views. Interested parties are also invited to consider whether they would like to submit an application for similar products on the UK market to enable the applications to be considered at the same time.

The Commission concluded that draft texts (or perhaps one text) for all the current applications would be drafted and would be discussed at a future Working Group meeting.

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