



BULLETIN INTENDED FOR INTERESTED PARTIES

## Update from the European Commission's Working Group meeting on health claims, 19 January 2015

There was discussion on generic descriptor applications and a number of health claims, including those mentioned below.

### **1. Presentation by the Commission of the application for the term 'probiotico' to be used as generic descriptor in Italy (Art. 1(4) of Regulation (EC) No. 1924/2006)**

There was discussion on the Italian authority application on the use of the term "Probiotico" as a generic descriptor. Generally "Probiotico" was not considered to be a generic descriptor as it is a health claim, in accordance with the Commission guidance on the use of the term "probiotic". Italy will consider the views expressed by Member States and the Commission.

### **2. Exchange of views on the use of term "Tonic" in the form of Tonic Water, Indian Tonic Water or Quinine Tonic Water (and equivalent translations) to be used as generic descriptor (Art. 1(4) of Regulation (EC) No. 1924/2006)**

The application for the use of the term "Tonic" in the form of Tonic Water, Indian Tonic Water or Quinine Tonic Water (in English) and the equivalent translations in the concerned Member States was discussed. The UK asked for the discussion because there was not consensus about this term being an Article 1(4) applicant (a generic descriptor), with some Member States considering the term a generic descriptor and some considering it a customary name under general food law and outside of the scope of the Regulation. The Commission reflected that to consider that "Tonic (and its variants)" is out of scope of Regulation (EC) No. 1924/2006 could cause difficulties in defining the "customary name".

### **3. Discussion on a health claim related to Monacolin K (EFSA opinions Q-2012-00736, Q-2012-00968) - exchange of views on a possible approach**

An Article 13.5 health claim, "*Monacolin K from red yeast rice contributes to the maintenance of normal blood cholesterol concentrations*" and an Article 14(1)(a) health claim "*A combination of artichoke leaf dry extract standardised in caffeoylquinic acids, monacolin K in red yeast rice, sugar-cane derived policosanols, OPC from French maritime pine bark, garlic dry extract*

*standardised in allicin, d- $\alpha$ -tocopheryl hydrogen succinate, riboflavin and inositol hexanicotinate reduces blood LDL-cholesterol concentrations. High LDL-cholesterol is a risk factor in the development of coronary heart disease*” received a positive EFSA opinion. Member States had concerns regarding the safety of red yeast rice food supplements which were noted.

**4. Discussion on the claim on Water-Soluble Tomato Concentrate (WSTC) I and II and normal platelet aggregation (Art.13(5) of Regulation (EC) No 1924/2006 – 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 ended in December 2014 and it will 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.

**5. Discussion on a draft Commission Regulation authorising health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health (Article13(5) of Regulation (EC) No 1924/2006 - SANCO/11042/2014, EFSA opinions Q-2013-00040, Q-2013-00615)**

There was limited discussion on proposed amendments to two health claims in Annex 1 of Regulation (EU) No. 432/2012 concerning sugar replacers.

**6. Discussion on a draft Commission Regulation refusing to authorise certain health claims made on foods and referring to children's development and health (Article 14(1)(b) of Regulation (EC) No 1924/2006 - SANCO/00069/2015, EFSA opinions Q-2008-140, Q-2008-148, Q-2008-193)**

Three Article 14(1)(b) claims relating to non-digestible oligo- and/or polysaccharides and calcium absorption, lactase for comfortable digestion, and dried plums/prunes contributing to normal bowel function received negative EFSA opinions as a cause and effect relationship has not been established between the consumption of the food constituent and the effect. There was no substantive discussion.

**7. 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 (Art.13(5) of Regulation (EC) No 1924/2006 - SANCO/00070/2014, EFSA opinion Q-2014-00022)**

The Article 13(5) claim relating to *Regular daily consumption of 1.37 g galacto-oligosaccharides from Bimuno® may reduce abdominal discomfort* 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 evidence provided was found to be insufficient to establish a cause and effect relationship. The Commission proposed rejecting the claim.

**8. Presentation of new EFSA opinions on Article 13(5) claims (Q-2014-00012, Q-2014-00044, Q-2014-00058, Q-2014-00073, Q-2014-00097, Q-2014-00126, Q-2014-00127, Q-2014-00153, Q-2014-00403 and Q-2014-00580) and Article 14(1)(b) (Q-2014-00059, Q-2008-159 and Q-2008-190)**

Four Article 13(5) claims relating to high-fibre sourdough rye bread and a reduction of post-prandial glycaemic responses, to “native chicory inulin” and maintenance of normal defecation by increasing stool frequency, to AlphaGOS® and a reduction of post-prandial glycaemic responses and to Nutriose®06 and a reduction of post-prandial glycaemic responses, all received positive EFSA opinions as a cause and effect relationship had been established between the consumption of the food constituent and the effect. The latter three claims will be discussed further at Working Group. For the claim relating to sourdough, conditions of use could not be established for the claim as the EFSA Panel considered that solid foods, including high-fibre sourdough rye bread, are generally not considered as an alternative to glucose solutions. It was discussed that the use of comparative claims should be related to the same category and this is not the case for the sourdough claim. The Commission proposed rejecting this claim.

The following Article 13(5) claims received negative EFSA opinions and will be discussed at a future Working Group on health claims:

- carbohydrate solutions and maintenance of physical performance during endurance exercise
- *Lactobacillus plantarum* TENSIA® in the semi-hard Edam-type ‘heart cheese of Harmony™’ and maintenance of normal blood pressure (BP)
- fat-free yogurts and fermented milks complying with the specifications ‘fat free’, ‘low in sugars’, ‘high protein’, ‘source of calcium’ and ‘source of vitamin D’ for nutrition claims and reduction of body and visceral fat mass while maintaining lean body mass in the context of an energy-restricted diet
- fat-free yogurts and fermented milks with live yogurt cultures complying with the specifications “fat free”, “low in sugars”, “high protein”, “source of calcium” and “source of vitamin D” for nutrition claims and maintenance of lean body mass in the context of an energy-restricted diet
- Teestar™ and a reduction of post-prandial glycaemic responses
- equimolar mixture (marketed under the trade names of Clarinol® and Tonalin®) of the two conjugated linoleic acid (CLA) isomers *c9,t11* and *t10,c12*, and “contributes to a reduction in body fat mass”.

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The following new Article 14(1)(b) health claims relating to docosahexaenoic acid (DHA) and contribution to normal brain development, selenium and protection of DNA, proteins and lipids and oxidative damage, zinc and normal growth, all received positive EFSA opinions. These health claims will be discussed further at the Commission Working Group on Foods for Specific Groups on 2 February 2015 and the Working Group on health claims will await the outcome of those discussions.

### **9. Exchange of views on the claim relating to slowly digestible starch – AOB item**

Member States discussed whether the authorised Article 13.5 health claim “*Consumption of products high in slowly digestible starch (SDS) raises blood glucose concentration less after a meal compared to products low in SDS*” was being used beyond expected flexibility of wording. Some claims including wording such as “*provides continuously and regularly carbohydrates for 4 hours*”, “*provides energy throughout morning*”, “*scientifically proven that it provides a regular glycaemic intake for 4 hours*”. Member States discussed that the EFSA opinion that assessed the claim was limited to a 2 hour glycaemia curve. The need to be strict in the principle of remaining close to the wording of the claim was stressed as this is fundamental to the legislation.

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