



BULLETIN INTENDED FOR INTERESTED PARTIES

## Update from the European Commission's Working Group meeting on health claims, 22 September 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 a health claim related to glycaemic carbohydrates and recovery of normal muscle function (contraction) after strenuous exercise (Q-2013-00234)**

There are some revisions to the COU (conditions of use). The wording has been revised so that “the beneficial effect is obtained with the consumption of carbohydrates from all sources at a total intake of 4g/kg body weight” so the claim would not need to be restricted to ‘sports foods’ as has previously suggested. The conditions of the claim also make it clear that the claim can be used “only for foods targeting adults who have performed highly intensive and/or long lasting physical exercise” rather than the previous draft wording “only for foods targeting individuals who have performed highly intensive and/or long lasting physical exercise”.

**2. Discussion on a draft Commission Regulation refusing to authorise five health claims related to glucose and energy-yielding metabolism (Art.13(5) of Regulation (EC) No 1924/2006 - SANCO/11446/2014, EFSA opinions Q-2012-00266, Q-2012-00267, Q-2012-00268, Q-2012-00269 and Q-2012-00270)**

We've reported discussions on these claims previously and concerns that they must not be used to encourage over consumption of glucose.

Although EFSA had published positive opinions on the five health claims, Member States (MS) discussed rejecting them on the basis that the use of these claims would convey a conflicting and confusing message to consumers. It 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 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 (these are the reasons given for rejecting previous health claims related to fat and sodium in recital 12 of Regulation 432/2012).

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### **3. Discussion on a draft Commission Regulation amending Commission Regulation 851/2013 as regards the conditions of use of an authorised health claim on the effect of cocoa flavanols on endothelium-dependent vasodilation (Art.13(5) of Regulation (EC) No 1924/2006 – SANCO/12060/2014, EFSA opinions Q-2013-00832)**

The claim will permit the consumption of high flavanol cocoa extract in capsule or tablet form. The draft Commission Regulation restricts the use of the claim in favour of the applicant for a period of five years. The claim can be made by the applicant for a period of 5 years from authorisation (rather than from the authorisation date of the original claim relating to cocoa beverages or for dark chocolate).

### **4. Discussion on the expiry of the restriction of the use of 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 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.

### **5. Discussion on a draft Commission Regulation refusing to authorise certain health claims made on foods and referring to children's development and health (Art.14(1)(b) of Regulation (EC) No 1924/2006 - SANCO/11095/2014, EFSA opinions Q-2008-174, Q-2008-134, Q-2008-131)**

In relation to the claim “Choline is needed for the development of brain of infants and young children from birth to three years” EFSA said choline is not an essential nutrient and there is no evidence to suggest that choline has a specific function in the brain.

It was suggested that the wording of recital 8 within the draft Regulation “On the basis of the data presented, the Authority concluded in its opinion, received by the Commission and Members states on 5 May 2014, that the claimed effect was general and non-specific” could be revised to “On the basis of the data presented, the Authority concluded in its opinion, received by the Commission and Members states on 5 May 2014, that the claimed effect was lacking in evidence in relation to a specific function in the brain”.

**6. Exchange of views on two health claims on meal replacements for weight control (Q-2008-2154 and Q-2008-2155) and their conditions of use referring to Directive 96/8/EC on foods intended for use in energy-restricted diets for weight reduction**

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 would need to be amended.

MS asked how the conditions of use for the two authorised meal replacement claims listed in Regulation 432/2012 will be amended when Directive 96/8/EC on foods intended for use in energy-restricted diets for weight reduction is repealed in July 2016 and what the new conditions of use will be.

The conditions of use for the two authorised meal replacement claims will need to be amended and discussions on these claims will take place as soon as the Commission legal service and experts within the foods for specific groups working group have been consulted.

**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/11004/2014, EFSA opinions Q-2013-00444, Q-2013-00757, Q-2013-00249)**

The Commission proposed rejecting these claims.

**8. 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/12039/2014, EFSA Question No Q-2013-00659, Q-2013-00783, Q-2013-00889, Q-2013-00893, Q-2013-00892, Q-2013-00756, Q-2013-00875)**

The Commission proposed rejecting these claims.

**9. Discussion on a draft Commission Regulation refusing to authorise certain health claims made on foods and referring to the reduction of disease risk (Art.14(1)(a) of Regulation (EC) No 1924/2006 - SANCO/12090/2014, EFSA opinions Q-2013-00595, Q-2013-00649)**

The Commission proposed rejecting these claims.

**10. Article 13(5) claims – EFSA opinions (Q-2014-00022, Q-2013-00973, Q-2013-00974)**

All three claims received negative EFSA opinions. The applicants have submitted written comments on their respective EFSA opinion. These comments have been submitted to EFSA for consideration.

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