



BULLETIN INTENDED FOR INTERESTED PARTIES

Follow-up questions from the European Commission's Working Group meeting on health claims held 20th June 2016

Your views are sought on the following item on health claims made on foods and referring to children's development and health, which we brought to your attention last month. We have now received additional questions from the European Commission as outlined below, and would appreciate your **comments by 26 July** to meet the Commission's deadline for responses.

Exchange of views with Member States on health claims made on foods and referring to children's development and health *Article 14(1)(b) of Regulation (EC) No 1924/2006*

Background: The Working Group on health claims previously discussed already authorised children health claims in the context of the twenty pending health claims specifically targeting infants and young children. A decision will need to be made on how to deal with these pending health claims, with reservations regarding the potential use of these claims on follow-on formulae. The European Commission has sent a list of questions covering the different categories of food (e.g. follow-on formulae, baby foods) in order to seek views on how to treat health claims for these food categories.

Health claims on regulated products for infants and/or young children (i.e. follow-on formulae, processed cereal-based food and baby food, bearing in mind that infant formulae can only make one health claim as laid down in Directive 2006/141/EC and, after 2020/2021, when delegated Regulation (EU) 2016/127 enters into application, all claims shall be prohibited for this product category):

Q1: What are your views on the use of health claims on such products? Should health claims not be authorised for such foods at all? Please bear in mind that any rejection decisions need to be justified. If you are supporting such rejection, please provide a justification that would be compatible with the rules of Regulation (EC) No 1924/2006.

If not,

BULLETIN INTENDED FOR INTERESTED PARTIES

Q2: What are your views concerning the possibility of not authorising at all health claims on nutrients whose presence is required by legislation (i.e. minimum amount)? Please explain the rationale for your answer.

Q3: Alternatively what do you think of the possibility of authorising the claims on such substances with a wording that clarifies that “all [category of foods] contain X. X contributes to Y”? Evidently, conditions of use for the claim would refer back to the compositional requirements laid down in the respective pieces of legislation.

Q4: Should health claims be authorised on nutrients whose presence is not required by legislation, how would you then set conditions of use?

Health claims on non-regulated products for infants and young children (i.e. food supplements for infants and young children and young-child formulae)

Q5: What are your views on the use of health claims on such products? Should health claims not be authorised for such foods at all? Please bear in mind that rejection decisions need to be justified. If you are supporting such rejection, please provide a justification that would be compatible with the rules of Regulation (EC) No 1924/2006.

If not,

Q6: Should you consider that such health claims should be authorised, how would you then set conditions of use?

Other questions

Q7: Do you have specific comments you want to make on nutrition claims for foods for infants and young children (6 months to 3 years)?

Q8: Delegated Regulation (EU) 2016/128 on foods for special medical purposes (FSMPs) shall enter into application in 2019/2020 and ban all nutrition and health claims on FSMPs. Do you agree that, taking this into account, no health claim should be authorised on FSMPs for infants and young children in the meantime, to ensure consistency?

Glossary:

Infants: children under the age of 12 months

Young children: children aged between one and three years

Children: according to Claims guidance (2007), the term should be understood as people from birth until an indicative age of 18 years (including infants and young children)

Please send your views to our mailbox nutritionlegislation@dh.gsi.gov.uk by **Tuesday 26 July**.

Reminder:

You are kindly requested to send information on the commercialisation of Monacolin K, contained at any level, as regards its classification (as food or as medicinal products) and labelling requirements. We welcome also any additional information on products containing monacolin K on the market as regards warnings and what is the maximum level allowed in products classified as foods? Do you have a safety concern with Monacolin K? Are you aware of incorrect use or of adverse effects to health related to food products containing Monacolin K?

Please send your information and views to our mailbox nutritionlegislation@dh.gsi.gov.uk by **Tuesday 26 July 2016**.

AOB:

We would like to inform you that the European Food Safety Authority (EFSA) has launched a public consultation on a **Draft Scientific and technical guidance for the preparation and presentation of a health claim application** (18 July 2016).

This document presents a common format for the organisation of information for the preparation of a well-structured application for authorisation of health claims which fall under Articles 13(5), 14, and 19 of Regulation (EC) No 1924/2006. This guidance outlines: the information and scientific data which must be included in the application, the hierarchy of different types of data and study designs (reflecting the relative strength of evidence which may be obtained from different types of studies) and the key issues which should be addressed in the application to substantiate the health claim.

The public consultation will remain open until **Monday 12 September 2016** and interested parties are invited to submit written comments directly to EFSA. The consultation document can be accessed via the following link: <https://www.efsa.europa.eu/en/consultations/call/160718a>.

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

BULLETIN INTENDED FOR INTERESTED PARTIES