
As provided for in Article 18(4) of Regulation (EC) No 1924/2006 Member States were consulted on a working document relating to a health claim provided for in Article 13(5) of that Regulation, which received a favourable assessment from the European Food Safety Authority (EFSA). The health claim related to the effects of slowly digestible starch on reduction of post-prandial glycaemic responses compared to rapidly digestible starch.

It was noted that the food constituent subject of the claim and the comparator food constituent were defined by the applicant according to the Englyst method and as such, EFSA considered that they were well characterised in relation to the claimed effect. Further, it was noted that EU legislation does not usually define methods of analysis for identifying and/or measuring food ingredients as these are rapidly evolving with technological and scientific progress. Delegations were asked to inform the Commission if 'slowly digestible starch' is understood in a coherent manner in different Member States. In addition, delegations were asked to provide information, either during the meeting or following the meeting in a short timeframe, on their possibilities to enforce the correct use of such claim, if it were to be authorised. Some Member States informed the Commission that the implementation of the method by their controlling authorities would not constitute a problem and others noted that the method is neither used nor preferred and the enforcement would be extremely difficult to ensure. One delegation noted that the method is already used in its territory and that even if the method was not used, Article 6(3) of Regulation (EC) No 1924/2006 allows controlling authorities to put the burden of the proof of compliance with an authorised health claim on the business operator.
The majority of Member States expressed concerns in relation to the possibility to mention the specific method used by the applicant which defined 'slowly digestible starch' in the measure authorising the health claim. In the absence of a single internationally accepted method measuring the starch digestibility, delegations stressed that no specific recognition should be granted to one method of analysis and especially in a Commission decision. In addition, it was noted that the wording of the claim should be improved to enable consumers to understand the beneficial effect if it were to be authorised.

The comments expressed during that discussion and the feedback that delegations will provide the Commission with, will be taken into account by the Commission in finalising its decision while discussions on the same issue are referred to the next expert working group.


The draft Commission Regulation was submitted to the Standing Committee in accordance with Article 17(1) of Regulation (EC) No 1924/2006. It aims at rejecting two health claims provided for in Article 14(1)(a) and two health claims provided for in Article 14(1)(b) of that Regulation.

The Commission presented the draft and the health claims therein, including the relevant EFSA opinions and the responses to the comments submitted by the applicant and/or members of the public pursuant to Article 16(6) of Regulation (EC) No 1924/2006.

Two applications related to the effects of ProteQuine®, a mixture of free amino acids, oligopeptides and nucleotides on increase of suppressed concentrations of secretory immunoglobulin A and reduction of the risk of common cold and of ProteQuine® with bovine lactoferrin on increase of suppressed concentrations of secretory immunoglobulin A and reduction of the risk of common cold with sore throat.

One application related to the effects of beta palmitate on increased calcium absorption for infants from birth to 12 months of age and the other application related to the effects of a combination of Lactobacillus delbrueckii subsp. bulgaricus strain AY/CSL (LMG P-17224) and Streptococcus thermophilus strain 9Y/CSL (LMG P-17225) on beneficial modulation of intestinal microflora for children from three to fourteen years of age.

The Commission explained to delegations that the legal drafting of the enacting terms of the measure has been modified compared to previous texts. The aim is to extend the period granted to operators and national controlling authorities to adapt to the new requirements of the draft Regulation to all claims used in commercial communications and not only to those used on the label of products. The Committee did not object to the new approach.

Vote: Favourable opinion by unanimity.

The draft Commission Regulation was submitted to the Standing Committee in accordance with Article 18(5) of Regulation (EC) No 1924/2006. It aims at refusing to authorise the use of two health claims foreseen in Article 13(5) of that Regulation.

The Commission presented the draft and the health claims therein, including the relevant EFSA opinions and the responses by EFSA to the comments submitted by the applicant and/or members of the public pursuant to Article 16(6) of Regulation (EC) No 1924/2006.

One application related to the effects of *Lactobacillus rhamnosus* GG (LGG) and maintenance of defence against intestinal pathogens and the other application related to the effects of *collagen hydrolysate* and maintenance of joint health in physically active people.

*Vote: Favourable opinion by unanimity.*


The draft Commission Regulation aims at establishing a list of permitted Article 13(1) health claims together with conditions of use and restrictions where appropriate.

The Commission presented the draft and informed the delegations of the implications of the measure regarding the implementation of Regulation (EC) No 1924/2006. The Committee received detailed explanations regarding the status of the entries in the consolidated list which are not on the permitted list as listed in the Annex of the draft measure.

More precisely, delegations had received notice of all the submitted Art. 13 claims for which the evaluation by the European Food Safety Authority and the consideration by the Commission and the Member States should be considered finalised. All such claims not on the permitted list would be entered in the Union Register with reasons why they are not authorised.
The Committee was also informed of all the submitted Article 13 claims for which the evaluation by the European Food Safety Authority (EFSA) and the consideration by the Commission and the Member States should not be considered finalised. Delegations also received notice of these claims to facilitate discussion. These include claims requiring further consideration by the risk managers before a decision on them can be taken; claims requiring a further assessment by EFSA; and claims on "botanical" substances that have not received an assessment by EFSA following a request by the Commission pending a reflection on how this is coherent with other EU legislation. All such claims will be listed on DG SANCO's website and will be considered on hold.

Several delegations expressed concern that these claims on hold would, by virtue of the draft Commission Regulation, no longer be able to stay on the market under the transitional measures in Regulation (EC) No 1924/2006. The Commission explained that the recitals of the draft measure under discussion are clarifying the status of the entries in the consolidated list and also that the transitional measures continue to apply for claims for which a decision had not yet be taken. Some asked for additional reassurance by references to transitional measures in the enacting terms. The Commission explained that the scope of the draft Commission Regulation is in accordance with its legal basis for the establishment of a list of permitted health claims and that therefore the enacting terms do not refer to transitional measures for claims which are outside the scope of the measure. One Member State was concerned that, while the draft Commission Regulation explained the status of all claims from the consolidated list, it needed to also address claims which had not been submitted into the process but were nevertheless on the market. The Commission explained that the draft Commission Regulation does address these claims in as much as once it applies, any claim that is neither in the permitted list nor still under consideration, would be subject to the prohibition provided for in Article 10 (1) of that Regulation.

An extensive discussion took place regarding several claims relating to substances which are subject to legislation in Member States with different outcomes as to the status of products containing them (foods or medicine). Member States expressed concern that the impact of this draft Commission Regulation might restrict national authorities in their autonomous decision making as to the classification of such products. In order to obviate this risk, a new recital was agreed to clarify that the adoption of a claim for a substance does not constitute a marketing authorisation or classify a substance as a foodstuff or for use in a foodstuff.

Several delegations noted that some of the claims in the draft Commission Regulation are expressed in complex scientific language and raised concerns about consumer understanding. No objections were raised by most delegations to the Commission's response that it was clear that some claims would be targeted at specific groups of consumers seeking such beneficial effects; that understanding among consumers is not uniform; and that despite many efforts by the Commission with the national experts on nutrition and health claims, it had been difficult to find enough common ground on different wording. In response to suggestions from delegations for additional guidance to address this and other issues, the Commission agreed to take this into consideration.
There was a lengthy discussion on certain key issues outlined below:

- The draft Regulation proposed adopting 224 positively assessed health claims covering around 500 of more than 4600 entries in the consolidated list submitted to EFSA for assessment. Eventually it was agreed that 222 health claims should appear in the permitted list, with two being removed from the list to be put on hold for further consideration by the risk managers (one claim on fructose and one claim on glycaemic carbohydrates).

- Two claims with a positive scientific assessment (one claim on fat, and one claim on sodium) were considered as not complying with other requirements of Regulation (EC) 1924/2006 and were not included in the permitted list.

- It was agreed that two claims on water should be restricted to water complying with legislation on mineral waters and/or drinking water, but consumers should be informed that the recommended 2.0 L per day to obtain the claimed effect can be from all sources.

- It was agreed that the conditions of use for two claims on meal replacement products should be extended to encompass all products complying with Directive 96/8/EC.

- The text of two different claims on konjac mannan (glucomannan) was standardised to ensure consistency.

- The issue was raised whether the conditions of use for one claim on beta-glucans should be extended to include beta-glucans from sources other than those listed in the proposed text. EFSA confirmed that on the basis of the evidence submitted this could not be done, and a specific assessment would be needed. The Committee accepted this view.

As a result, the Annex of the draft Commission Regulation was revised accordingly. The Committee also agreed to numerous technical and/or editorial adjustments for the Annex of the draft measure under discussion designed to ensure its overall internal consistency, and its consistency with the Annex on nutrition claims to Regulation (EC) No 1924/2006.

*Vote: Favourable opinion by qualified majority (390 in favour; 19 against, 36 abstained).*


The draft Commission Regulation aims at establishing implementing rules for the use of the procedure under Article 8 of Regulation (EC) No 1925/2006 to prohibit, restrict or place under Union scrutiny a substance other than a vitamin or a mineral.
The Commission presented the draft measure to the Committee and the changes that were made to the draft text following an exchange of views at the Standing Committee meeting of 13 October 2011.

During the exchange of views, some delegations expressed their concerns regarding the difficulty for a Member State to fulfil the condition of providing actual dietary intake data for a substance in support of a request. The draft text was slightly amended to take these concerns into consideration. However, the Commission pointed out that the requirement to provide dietary intake data of the substance as laid down in Article 4 (1) (b) of the draft measure was necessary to guarantee that the conditions laid down by Regulation (EC) No 1925/2006 were met.

The German delegation asked for the following statement, reflecting its own interpretation, to be included in the summary record of the meeting:

"To the German understanding the procedure under Article 8 applies also to substances that are already banned in one or more Member States, such as the ten substances that Germany proposed in 2009 for inclusion in Annex III of Regulation (EC) Nr. 1925/2006. Article 8 paragraph 1 of Regulation (EC) No 1925/2006 and Article 4 paragraph 1 lit. (a), subparagraph 2 of the Implementing Regulation do not preclude this interpretation, even if the applicant Member State cannot provide a market proof by reason of its national ban. This understanding corresponds also with recital 22 of Regulation (EC) No 1925/2006."

Vote: Favourable opinion by unanimity.


In order to be informative for the consumer and at the same time providing the nature of the product, it was agreed to amend the designation on the labelling. The designation on the labelling will be gum base followed by its chemical name in brackets, 'gum base (chemical name)'.

Vote: Favourable opinion by unanimity.


The draft Commission Regulation was submitted to the Standing Committee in accordance with Article 18(5) of Regulation (EC) No 1924/2006. It would refuse to authorise the use of three health claims foreseen in Article 13(5) of that Regulation.
The applications subject to this draft measure were based on newly developed scientific evidence. One application related to the effects of "hypo-caloric snacks (KOT products)" on reduction of the adipocytes size at the abdominal level, in the context of low-calorie diet. The second application related to the effects of peptides Isoleucyl-prolyl-proline (IPP) and Valyl-prolyl-proline (VPP) on maintenance of blood pressure and the third application related to the effects of Appl'In® polyphenolic apple extract powder (Malus domestica) on decrease of glycaemic responses in women.

The draft Regulation will be referred for further discussions at expert level and put to the vote of the Committee in a future meeting.


The draft Commission Regulation was submitted to the Standing Committee in accordance with Article 17(1) of Regulation (EC) No 1924/2006. It would authorise the use of one health claim provided for in Article 14(1)(a) of that Regulation.

The application related to the effects of vitamin D on the reduction of the risk of falling, which is a risk factor in the development of bone fractures. During the discussion it was noted that the conditions of use suggested by EFSA, i.e.: 20µg of daily intake of vitamin D, are considered to be too high in some Member States. The Commission informed the Committee that EFSA has accepted a Mandate of the Commission requesting if necessary, to propose revised tolerable upper intake levels for vitamin D. Given that such advice will play a decisive role in the setting of conditions of use of the claim, risk managers agreed to wait for the EFSA advice before proceeding with a decision on the claim.

The draft Regulation will be referred for further discussions at expert level and put to the vote of the Committee in a future meeting, following the advice by EFSA on the safety in use of vitamin D.