
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 two health claims provided for respectively in Article 14(1)(a) and in Article 14(1)(b), and would reject one health claim provided for in Article 14(1)(a) of that Regulation.

More particularly, one application related to the effects of oat-beta glucan on the reduction of blood cholesterol, which is a risk factor in the development of coronary heart disease. One application related to the effects of thiamin on the maintenance of normal neurological development and function of children. One application related to the effects of a fermented milk containing lactic acid bacteria (Actimel®) on the reduction of Clostridium difficile toxins in the gut (of susceptible ageing people), which is associated with the incidence of acute diarrhoea.

The Commission presented the draft and the health claims therein, and a number of issues were raised. As these issues were of a technical nature, the draft Regulation will be referred for further discussions at experts' level and put to the vote of the Committee in a future meeting.

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 EFSA assessment.

More specifically, the health claim related to the effects of a range of modified non-alcoholic beverages, with fermentable carbohydrate content less than 1g per 100ml, pH display between 3.7-4.0 and calcium in a range from 0.3 to 0.8 mol per mol acidulant ('toothkind' drinks), on the reduction of tooth demineralisation, when replacing sugar-containing, acidic, non alcoholic drinks.

According to EFSA, the evidence submitted supported the claim in cases of consumption of juice drinks four times daily and of sugar-containing, acidic drinks seven times daily, as such consumptions are shown to lead to tooth demineralisation. While concluding favourably, EFSA noted that the evidence supports the proposed claim only in cases of such frequent consumption of juice drinks and sugar-containing, acidic drinks.

Many delegations consider that such patterns of consumption are not typical and therefore the claim could be misleading for consumers who do not have those consumption patterns. In addition, delegations stated that such patterns are not recommended by national dietary guidelines in the Union, and allowing such claim to be used could encourage or condone excess consumption of juice drinks and sugar-containing, acidic, non alcoholic drinks. Further, delegations stressed that the claim would be contrary to Article 3(b) of Regulation (EC) No 1924/2006, as it gives rise to doubt about the safety and/or nutritional adequacy of other foods, and therefore, it should not be permitted.

On the other hand it was noted that it may be considered that the claim is valid for certain groups of the EU population that consume frequently on a daily basis sugar-containing, acidic, non-alcoholic beverages, and this could be justifiable grounds to permit the claim.

The comments expressed during that discussion will be taken into account by the Commission in finalising its decision while further discussion on the issue was referred to the next experts' working group.

3. **Exchange of views on a request by Germany to initiate the procedure under Article 8 of Regulation No 1925/2006 to place "certain other substances" in Annex III of the Regulation (YA)**

An exchange of views was held on the request by Germany to initiate the procedure under Article 8 of Regulation (EC) No. 1925/2006 in relation to the addition to foods of the polyunsaturated omega-3 fatty acids, docosahexaenoic acid (DHA), eicosahexaenoic acid (EPA) and docosapentaenic acid (DPA).
The German delegation explained that this request is based on the scientific opinion of the Federal Institute for Risk Assessment (BfR) which, having used two scenarios to model the increase in the intake of EPA/DHA/DPA via fortified foods, concluded on that basis that intakes of EPA/DHA/DPA may reach levels twice or three times above those reasonably expected to be ingested under normal conditions in a balanced and varied diet. The first model scenario includes four fortified foods that are currently available on the German market and the second model scenario ("worst-case scenario") includes nine foods that were hypothetically fortified with DHA-rich microalgal oil at the maximum permitted DHA levels laid down in Commission Decisions 2009/778/EC, 2009/777EC and 2003/427/EC on novel food authorisations. In the first scenario, 3.7% of the German population would consume more than 1.5g of EPA/DHA/DPA per day which is the recommended upper intake level set by the BfR. In the worst-case scenario, 16.7% of the German population would consume more than 1.5g/day. The BfR, in its opinion, also refers to potential harmful effects of excessive consumption of omega-3 fatty acids. That opinion had been sent to the delegations in advance of the meeting.

In opening the discussion, the Commission recalled that the conditions that must be fulfilled in order to initiate the procedure of Article 8 of the Regulation are laid down in paragraph 1 of the same Article. These conditions are that "a substance other than vitamins or minerals, or an ingredient containing a substance other than vitamins or minerals, is added to foods or used in the manufacture of foods under conditions that would result in the ingestion of amounts of this substance greatly exceeding those reasonably expected to be ingested under normal conditions of consumption of a balanced and varied diet and/or would otherwise represent a potential risk to consumers."

On the other hand, it was pointed out that the BfR's exposure calculations are based on the "worst-case scenario". As stated by the BfR in its scientific opinion this is "a conservative procedure with a high degree of certainty which nonetheless is not necessarily achieved in reality".

During the discussion, amongst the Member States which took position on the issue, two were supportive of the German request, while two others expressed the view that the use of the substances at stake is currently not of concern, and it is doubtful that the conditions for proceeding with Article 8 are met.

The Commission observed that, while the European Food Safety Authority (EFSA) has not established a tolerable upper intake level for omega-3 fatty acids, and the US Food and Drug Administration recommended in 2003 as a matter of prudence not to exceed 3g/day of those substances, the BfR has set a recommended upper intake level of 1.5g/day.

As the German delegation was asked to clarify how this value was determined, it indicated that all relevant data would be made available on request.

Finally, the Commission reminded the Member States that EFSA in its opinion on Labelling Reference Values for n-3 and n-6 polyunsaturated fatty acids (adopted on 30 June 2009) stated that the observed average intakes of EPA plus DHA in adults in some European countries vary between 80mg/day and 420mg/day. EFSA observed that these values are lower than the recommended intakes of 200-500mg/day for cardio-protective effects.
It was concluded that there is a need to reflect on the request by Germany in relation to EPA/DHA/DPA and that any decision would take into account the views presented by the delegations and the elements mentioned during the Committee meeting.

4. **Exchange of views on a request by Sweden on contaminant in baby foods (AVS)**

The Swedish National Food Administration informed the Committee on the results of analysis carried out by the Swedish Institute of Environmental Medicine (IMM) on 18 products intended to infants and young children as regards the levels of certain minerals and heavy metals. High levels of manganese, cadmium and arsenic were reported in particular. The National Food Administration asked for the Commission and Member States' views and experience on that issue.

The Commission explained that manganese is not per se a contaminant but an essential nutritional element, and compositional requirements have been set for it in the specific legislation applying to foods for infants and young children (Directives 2006/141/EC, 2006/125/EC and 1999/21/EC). Regarding infant formulae and follow-on formulae, the minimum and maximum levels were fixed on the basis of a report of the Scientific Committee on Food (SCF).

However, the Swedish delegation reported that, while the measured levels are in line with the legislation, high levels of manganese might be of concern when considering total dietary intakes.

As regards food contaminants such as cadmium, arsenic and lead, the results of IMM are confirming those of the European Food Safety Authority (EFSA) database. The Commission is currently reviewing Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foods following recent EFSA opinions on cadmium, lead and arsenic. In this context, foods for infants and young children are already under consideration.

It was agreed that more data are needed in order to consider both issues adequately. The Commission invited Member States to submit any relevant data they have and proposed to discuss this issue further.


The draft Commission Regulation, already presented to the Standing Committee on 6 December 2010, aims at adopting a decision, in accordance with Article 18(5) of Regulation (EC) No 1924/2006, refusing to authorise the use of two health claims provided for in Article 13(5) of that Regulation. The applications were based on newly developed scientific evidence with a request for protection of proprietary data, as provided for in Article 13(5) of that Regulation.
For one of the health claims included in the draft measure, regarding the effects of a fermented milk product containing *Lactobacillus casei Shirota* (Yakult®), comments were received pursuant to Article 16(6) of the Regulation regarding the scientific assessment. The comments were transmitted to EFSA for its consideration. Given that EFSA had not yet informed risk managers of its response to those comments, the Commission revised the draft and removed the specific health claim from the draft Regulation submitted for the opinion of the Committee.

The Commission proceeded to present the revised draft and the health claims therein, including the relevant EFSA opinions. An exchange of views took place and the Committee delivered a favourable opinion by unanimity.


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 authorising two health claims and at rejecting one provided for in Article 14(1)(a) of that Regulation.

More specifically, the two health claims to be authorised refer to the effects of sugar free chewing gum on the reduction of two risk factors, namely tooth demineralisation and plaque acids, in the development of dental caries. The rejected claim referred to the reduction of the risk of chronic venous insufficiency by increasing the microcirculation.

The Commission presented the draft and the health claims therein, including the relevant EFSA opinions. An exchange of views took place and the Committee delivered a favourable opinion by unanimity.


The draft Commission Decision was submitted to the Committee pursuant to Article 20 of Directive 2000/13/EC.


The draft Regulation provides *inter alia* for mandatory labelling requirements for the above-mentioned products to which other foodstuffs or ingredients have been added. It also sets out the labelling requirements for cheese and other specific dairy products and preparations of dairy products.
The Latvian delegation informed the Committee that, following the negative opinion of the Commission on Articles 8-11, 13, 17 and 19 of the notified draft Regulation, Latvia decided to withdraw the aforesaid draft measures.

The Commission took note of this statement highlighting that Latvia should proceed with a formal withdrawal of the provisions of Articles 8-11, 13, 17 and 19 of the notified draft Regulation and transmit to the Commission the final modified version of the draft measure.

Therefore, the Committee did not consider further the draft Commission Decision.


Chromium Picolinate is on the market in the EU only as an ingredient to food supplements. Therefore, a novel food authorisation is required before Chromium Picolinate may be included into the list of Vitamins and Minerals under Regulation (EC) 1925/2006. The authorisation under the Novel Food Regulation is without prejudice to other legal requirements.

The draft proposal received a favourable opinion by qualified majority (313 votes in favour; 32 votes against).


In their opinion(s) EFSA stated that the safety of the oil containing conjugated linoleic acid (CLA) products had been established. However, they also stated that the safety of CLA consumption for periods longer than six months has not been established.

Member States considered that the risk management measures needed further discussion at expert level to find a solution for a possible authorisation of CLA that addresses in a more appropriate way the concerns with respect to intakes of CLA for periods of more than six months.
11. Any other business

Portugal asked information about an Italian law about which they had read press reports relating to labelling of country-of-origin. The Commission informed that it was expecting the relevant notification and was not in a position to provide further information on the contents of such a measure.

The Commission informed the Committee that the European Parliament will have a debate and vote on a draft Resolution, under its right of scrutiny, regarding a draft Commission Regulation which received the favourable opinion of the Committee at its meeting of 6 December 2010, more particularly, regarding the health claim "Docosahexaenoic acid (DHA) intake contributes to the normal visual development of infants up to 12 months of age", which was proposed to be authorised.