EUROPEAN COMMISSION

Health and Food Safety Directorate General

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Standing Committee on Plants, Animals, Food and Feed
Section *General Food Law*
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SUMMARY REPORT

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) amending Annex II to Directive 2002/46/EC of the European Parliament and of the Council as regards iron hydroxide adipate tartrate used in the manufacture of food supplements.

A Commission representative presented the draft Commission Regulation which aims to include iron hydroxide adipate tartrate in Annex II to Directive 2002/46/EC and thereby permits its use as a new source of iron in food supplements.

The substance has received a favourable scientific assessment by the European Food Safety Authority and is included in the Union list of novel foods laid down in Commission Implementing Regulation (EU) 2017/2470. During the exchange of views, three Member States noted that a footnote making reference to the novel food authorisation of the substance should be provided for by the draft measure and inserted in Annex II to Directive 2002/46/EC to enable food business operators and control authorities to make the link between the two legal frameworks. The Committee agreed to insert in that Annex a footnote making reference to the Union list of novel foods.

Vote taken: Favourable opinion.

M.01 Request from Finland – on the classification of a product called Souvenaid marketed as a food for special medical purposes for the dietary management of early Alzheimer

Finland explained that different Member States' competent authorities seem to have divergent approaches to the classification of Souvenaid as a food for special medical purposes (FSMP) or not. In order to ensure a harmonised classification of the product and the free circulation of goods in the Internal Market, Finland asked the Commission to consider launching the procedure provided for in Article 3 of Regulation EU (No) 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control (FSG Regulation), which empowers the Commission to adopt interpretation decisions on whether a given food is appropriately classified as FSMP or not. Furthermore, Finland invited other Member States to clarify on what grounds they classify the product in question as FSMP or not.

Three Member States expressed their support for an EU harmonised approach while noting that their national agencies had assessed Souvanaid and concluded that the product did not fulfil the definition of FSMP provided for in the FSG Regulation. Two other Member States expressed their support for an EU harmonised approach. One Member State informed the Committee of the assessment of its national agency according to which people with early Alzheimer have no special dietary needs. Another Member State noted that the product in question had been placed on their market as FSMP with no reference to Alzheimer disease but for the dietary management of "cognitive decline linked to age". Finally, one Member State was of the view that the product did not fulfil the definition of FSMP and therefore such a case did not necessitate the launch of the Article 3 procedure.

The Commission took note of Member States views on the matter and emphasized the followings:

- Considering the composition of the product that mainly contains vitamins and minerals, it appears that there might be alternative ways of satisfying the nutritional needs of the patients suffering from early Alzheimer.
- Based on the information shared by some Member States, patients suffering from early Alzheimer seem to have no special dietary needs.
- In the course of their enforcement activities, Member States' competent authorities could rely on the opinions of the abovementioned national agencies, based on which Souvanaid cannot be considered as FSMP.
- The statement "for the dietary management of cognitive decline linked to age" should be considered as a claim the use of which is prohibited on FSMPs.

The Commission finally noted that based on the abovementioned elements, it does not see the need to launch the procedure provided for in Article 3 of the FSG Regulation for the purpose of the classification of Souvanaid.

M.02 Request from Denmark – for an update on the status of the revision of the Food Information to Consumers Regulation, in particular on front-of pack nutrition labelling and the setting of nutrient profiles

A Commission representative explained that the work to review the Regulation on Food Information to Consumers is ongoing.

Like for all legislative proposals, an impact assessment is being prepared, based on scientific evidence provided by the European Food Safety Authority and the Joint Research Centre, and on consultations with citizens, stakeholders and targeted surveys with Member States, businesses, SMEs, and consumer/health organisations.

Given the complexity of this work, focus is on gathering robust evidence and data, particularly as regards impacts of food labelling on consumer behaviour, given the objective of empowering consumers to make informed, healthy and sustainable food choices.

M.03 Request from Belgium –working group meetings on maximum amounts of vitamins and minerals in food supplements and fortified foods

A Commission representative clarified that the last meeting of the task force on maximum amounts took place in March. A working group meeting with all Member States was announced for May to discuss and exchange on the methodology to be followed for setting maximum amounts but the meeting could not take place and no further information can be provided at this stage.