



EUROPEAN COMMISSION

HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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**SUMMARY REPORT OF THE
STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED
HELD IN BRUSSELS ON 07 MARCH 2017
(Section General Food Law)**

CIRCABC Link: <https://circabc.europa.eu/w/browse/15632079-81d5-4263-b8c8-417865f97070>

A.01 Exchange of views on the Romanian notification of the draft “Law regulating the marketing of breast-milk substitutes” as notified on 1 February 2017 to the Commission according to Article 45 of Regulation (EU) No 1169/2011.

The Romanian delegation provided a presentation of the notified measure and of its justification. Romania explained in particular that the measure is aimed at increasing low breastfeeding rates, which constitute an important public health problem in Romania and are incompatible with children's right to health as enshrined in the Romanian Constitution and in the UN Convention on the rights of the child.

The Commission summarized the procedural steps related to the Romanian notification and, in particular, recalled that the draft “*Law regulating the marketing of breast-milk substitutes*” was first notified on 17 October 2016 to the Commission and Member States within the framework of the notification procedure laid down by Directive (EU) 2015/1535 (2016/554/RO). On 20 February 2017, the Romanian authorities notified the Commission and Member States also under the procedure provided in Article 45 of Regulation (EU) No 1169/2011, taking into account that the Law contains provisions which apply to the labelling of foods (“breast-milk substitutes” intended for feeding infants and young children up to two years of age and any liquid, semi-solid or solid food designed to be given to infants during the first six months of life, or human milk fortifiers).

During the discussion, the Romanian authorities also informed the Committee that the measure in question has in fact already been adopted by the Romanian Parliament (without prior notification as required by Article 45 of Regulation (EU) No 1169/2011) but it has not entered into force yet.

A number of delegations took the floor. While welcoming the objective of the measure and confirming their commitment to breastfeeding support, they raised a number of questions on the compatibility of the measure with existing provisions of EU law applicable to foods for infants and young children.

The Commission clarified that, from a procedural point of view, Member States must notify measures when they are at draft stage.

A.02 Exchange of views of the Committee on a Working document prepared by the Commission services for consultation of Member States on two health claims related to "Vitamin C and protection from oxidative damage" (Question EFSA No Q-2008-175) and to "'Nutrimune®' and immune defence against pathogens" (Question EFSA No Q-2016-00008) pursuant to Regulation (EC) No 1924/2006 (Art. 14(1) of Regulation (EC) No 1924/2006).

As provided for in Article 17(1) of Regulation (EC) No 1924/2006, Member States were consulted on two health claims provided for in Article 14(1) of that Regulation, for which the European Food Safety Authority (EFSA) published its opinions on 19 July 2016. More specifically, the applications were related to the effect of:

- Vitamin C and protection from oxidative damage
- 'Nutrimune®' and immune defence against pathogens

The Commission presented the EFSA opinion and the health claim on Vitamin C and protection from oxidative damage which will be also subject to the discussions currently taking place on children claims.

In relation to the health claim on Nutrimune® and immune defence against pathogens, the Commission informed the delegations that the applicant had submitted scientific comments on the Authority's opinion and that the Commission would re-discuss this claim with the delegation once the Authority's response to these comments becomes available.

In all cases, the matter will be referred for further discussion at expert's level.

A.03 Exchange of views of the Committee on the request by the Estonian authorities to adopt an interpretation decision pursuant to Article 3 of Regulation (EU) No 609/2013 on a product placed on the market in Estonia as food for special medical purposes.

At the request of Estonia, the Committee held an exchange of views on the classification of a product as food for special medical purposes (FSMP).

The product in question is a capsule containing a combination of L-carnitine, L-arginine, coenzyme Q10, vitamin E, zinc, folic acid, glutathione and selenium. According to the manufacturer, the product is intended to meet the particular nutritional requirements of male patients who are affected by infertility/sperm disorders, helps improve sperm quality and should be placed on the market in Estonia as FSMP for the dietary management of fertility disorders. The Estonian authorities do not agree with the operator and, in order to clarify the situation, asked the Commission to rule on the product's classification by adopting an interpretation decision pursuant to Article 3 of Regulation (EU) No 609/2013.

The Commission first opened the floor to hear the comments of Member States. The great majority of delegations that intervened were of the view that the product in question complies with the definition of food supplement, provided in Article 2(a) of Directive 2002/46/EC. These Member States referred to the definition of FSMP, provided in Article 2(2)(g) of Regulation (EU) No 609/2013, whereby these products are "*(...) intended for the exclusive or partial feeding of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients contained therein, or metabolites, or with other medically-determined nutrient requirements, whose dietary management cannot be achieved by modification of the normal diet alone*". In light of the definition, according to these Member States, the product cannot be classified as an FSMP taking into account that it provides a combination of vitamins, minerals and other substances that can be easily consumed with a modification of the normal diet (including through consumption of food supplements with similar composition). Some of these delegations added that the product was originally notified as FSMP in their territory but that, after bilateral discussions with national competent authorities, the operator reconsidered its position and placed it on the market as food supplement. Two delegations noted that if the product is presented for the prevention/treatment of a disease, it should be classified as medicinal product. One delegation recalled that an exchange of views with the Commission and Member States on the classification of this product already took place some years ago and the Commission agreed that it should be classified as food supplement.

A few Member States' delegations reported the presence of the product on their market as FSMP and one of these stated that it considers the product as complying with the definition of FSMP.

In its intervention, the Commission explained that it continues to agree with those Member States that consider the product as not corresponding to the FSMP definition. The Commission noted that, according to the definition of FSMP, these products are intended for the feeding of patients that, for different reasons, cannot (i.e. they find it impossible, impractical, unsafe or nutritionally/clinically disadvantageous to) satisfy their specific nutritional requirements through the exclusive consumption of foods other than FSMP. This does not seem to be the case for the product described by the Estonian delegation.

Regarding the request to adopt an interpretation decision pursuant to Article 3 of Regulation (EU) No 609/2013, the Commission referred to the exchange of views that took place in the Standing Committee meeting of 10 October 2016: Article 3 empowers the Commission to take decisions to ensure the uniform implementation of the legislation but does not replace the regime laid down in the general food law Regulation (EC) No 178/2002 which leaves national authorities with the general responsibility for enforcing EU food law (and in this context to consider, on a case-by-case basis, whether a product correctly falls under the scope of a specific piece of legislation). For this reason, likely candidates for these decisions should be products for which Member States have diverging views on their classification, which could result in concrete problems for their free circulation in the Internal Market.

The Commission noted that while the Committee does not unanimously agree on the status of the product presented by the Estonian delegation, there is a great majority of delegations which considers it a food supplement. The Commission also explained that it is currently preparing guidelines on the classification of FSMP, which will provide useful elements to all operators and national competent authorities to understand the definition of FSMP. The Commission is confident that the guidelines will help ensuring uniform implementation of the legislation for cases like the one presented by the Estonian delegation.

Against this background, the Commission concluded that it would find it disproportionate (taking into account the limited divergences of views among Member States) and premature (taking into account the forthcoming adoption of the guidelines) to adopt an Article 3 decision on the product in question at this stage. However, it added that pursuant to Article 3 of Regulation (EU) No 609/2013, the discretion to adopt "interpretation decisions" remains entirely in the hands of the Commission, so that the issue could be further reconsidered should problems on the classification of the product persist in the future.

A.04 Exchange of views on the Romanian notification of the draft "Law on setting up certain mandatory additional measures for labelling fresh milk for consumption and dairy products" as notified on 20 February 2017 to the Commission according to Article 45 of Regulation (EU) No 1169/2011.

The Romanian delegation provided a presentation of their notified texts (national Law corresponding to a basic act and an amendment to this Law) and their justifications.

With regard to the measures setting up certain mandatory additional labelling for fresh milk for consumption and dairy products it was explained that there has been a strong consumer demand to require indication for the country of origin of raw milk. It was explained that the basic act was already adopted by the Romanian Parliament on 5 May 2016 but is not in force until the Commission has not communicated its decision. Romania further explained that on the contrary the amendments notified in conjunction with the act adopted in 2016, have not been adopted by the Romanian Parliament.

Romania explained that the intention is that both fresh milk used for consumption and raw milk used as ingredient in dairy products are covered by the measures. It was further clarified that the measures are not limited in time but limited to foods produced in Romania.

During the discussions several Member States strongly criticised the increasing number of national notifications requiring mandatory origin indication.

The Commission clarified the procedural framework applicable to national measures. Any additional labelling mandatory particulars have to be notified under Regulation (EU) No 1169/2011, and other labelling provisions have to be notified via the TRIS system for technical standards.

B.01 Exchange of views and possible opinion of the Committee 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.

This 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 three health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health, pursuant to Article 13(5) of Regulation (EC) No 1924/2006.

More specifically, the applications subject to this draft measure relate to the effects of:

- Consumption of low-fat fermented milk with a combination of fructo-oligosaccharides (FOS) and live *Lactobacillus rhamnosus* GG (ATCC 53103), *Streptococcus thermophilus* (Z57) and *Lactobacillus delbrueckii* subsp. *bulgaricus* (LB2) helps to reduce recurrence of lip cold sores caused by Herpes simplex virus infection in healthy susceptible individuals.
- FHI LFC24 helps to regulate blood glucose levels following food consumption.
- V0137, in association with physical and intellectual training, helps to slow the age-related cognitive decline in domains such as memory and executive function.

The European Food Safety Authority (EFSA) gave an unfavourable opinion to these health claims and accordingly they should not be authorised. The Commission presented the draft and the health claims therein.

There were no comments or observations by the delegations in the substance of the draft measure.

Vote taken: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee 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.

This 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 three health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health, pursuant to Article 13(5) of Regulation (EC) No 1924/2006.

More specifically, the applications subject to this draft measure relate to the effects of:

- Fabenol[®] Max reduces the absorption of carbohydrates
- DHA contributes to improved memory function
- Polydextrose contributes to an improved bowel function by increasing stool bulk

The European Food Safety Authority (EFSA) gave an unfavourable opinion to these health claims and accordingly they should not be authorised. The Commission presented the draft and the health claims therein.

There were no comments or observations by the delegations in the substance of the draft measure.

Vote taken: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Regulation refusing to authorise a health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health.

This 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 one health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health, pursuant to Article 13(5) of Regulation (EC) No 1924/2006. More specifically, the application subject to this draft measure relates to the effects of short-chain fructooligosaccharides from sucrose and the maintenance of normal defecation.

The European Food Safety Authority (EFSA) gave an unfavourable opinion to this health claim and accordingly it should not be authorised. The Commission presented the draft and the health claims therein.

There were no comments or observations by the delegations in the substance of the draft measure.

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Regulation correcting the Bulgarian, Finnish, German, Portuguese and Spanish language versions of Regulation (EU) No 432/2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health.

The Commission presented the draft Regulation which aims at correcting language mistakes in the Bulgarian, Finnish, German, Portuguese and Spanish versions of the list of Regulation (EU) No 432/2012 concerning two authorised health claims made on meal replacement for weight control. Two affected delegations welcomed the

correction of the mistakes and underlined the importance of legal clarity as regards of applicable language versions.

Vote taken: Favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) amending Directive 2002/46/EC of the European Parliament and of the Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards organic silicon (monomethylsilanetriol) and calcium phosphoryl oligosaccharides (POs-Ca®) added to foods and used in the manufacture of food supplements.

The draft Commission Regulation aims at including the substances organic silicon (monomethylsilanetriol) and calcium phosphoryl oligosaccharides (POsCa®) in Annex II to Directive 2002/46/EC and thereby permitting their use in the manufacture of food supplements. It also aims at including the substance calcium phosphoryl oligosaccharides (POsCa®) in Annex II to Regulation (EC) No 1925/2006, thereby permitting its addition to foods. The substances have received a favourable scientific assessment by the European Food Safety Authority (EFSA).

A delegation asked for clarification regarding the authorisation of calcium phosphoryl oligosaccharides (POsCa®) for use in Foods for Special Medical Purposes (FSMP). The Commission explained that as this requires a different procedure to the one used to include a substance in the Annexes to Directive 2002/46/EC and to Regulation (EC) No 1925/2006, a separate draft measure is being prepared by the Commission.

A delegation asked for inclusion of certain conditions of use in the Annexes to Directive 2002/46/EC and to Regulation (EC) No 1925/2006 for the substance calcium phosphoryl oligosaccharides (POsCa®), in line with the recommendations made by EFSA in its scientific opinion. The Commission clarified that Directive 2002/46/EC and Regulation (EC) No 1925/2006 do not provide the possibility to include conditions of use in the Annexes but that nevertheless the recommendations provided by the EFSA opinion must be taken into consideration by food business operators. Therefore, Recital 9 of the draft measure states that it follows from the scientific opinion by EFSA that the addition of the substance to foods and its use in the manufacture of food supplements is not of a safety concern “provided that certain conditions are respected”.

Certain Member States took the opportunity to reiterate their support for the setting of maximum amounts of vitamins and minerals in foods at EU level.

Vote taken: Favourable opinion.

C.01 Exchange of views of the Committee on a draft Commission Implementing Regulation authorising a health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health and amending Regulation (EU) No 432/2012. (Consultation of Member States)

As provided for in Article 18(4) of Regulation (EC) No 1924/2006 Member States were consulted on the authorisation of one health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health, namely, a health claim on creatine in combination with resistance training and improvement in muscle strength.

The health claim submitted pursuant to Article 13(5) obtained a favourable assessment by the European Food Safety Authority (EFSA) and accordingly it should be authorised. The Commission presented the draft Regulation and no comments or observations were raised by the delegations on this draft measure. One delegation made an editorial suggestion which was considered to improve the text and was taken into account.

Further to this exchange of views and the consent of the Member States, the Commission will continue with the authorisation of this claim.

C.02 Exchange of views of the Committee on a draft Commission Implementing Regulation authorising a health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health and amending Regulation (EU) No 432/2012. (Consultation of Member States)

As provided for in Article 18(4) of Regulation (EC) No 1924/2006 Member States were consulted on the authorisation of one health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health, namely, a health claim related to lactitol and the maintenance of normal defecation.

The health claim submitted pursuant to Article 13(5) obtained a favourable assessment by the European Food Safety Authority (EFSA) and accordingly it should be authorised. The Commission presented the draft Regulation and no comments or observations were raised by the delegations on this draft measure.

Further to this exchange of views and the consent of the Member States, the Commission will continue with the authorisation of this claim.

M.01 Italy request for an exchange of views on the classification of a product in capsule form containing Palmitoylethanolamide (PEA) as food for special medical purposes (FSMP) for the dietary management of neuroinflammation.

At the request of Italy, the Committee held an exchange of views on the classification of a product in capsule form containing Palmitoylethanolamide (PEA) as food for special medical purposes (FSMP) for the dietary management of neuroinflammation.

The Italian delegation informed the Committee that the product was for many years placed on the market in Italy as FSMP and that the Italian authorities agreed with the operator on its classification as FSMP. Following the numerous discussions that took place in most recent years on the classification of FSMP (including in the context of the Standing Committee), and taking into account that other Member States had

doubts on the classification of the specific product as FSMP, the Italian authorities decided to look again into the product classification. After having exchanged with the food business operator, and taking into account the Scientific and technical guidance recently adopted by EFSA on the data that the Authority considers appropriate to assess correspondence of products to the definition of FSMP, the Italian authorities came to the conclusion that the product in question does not in fact correspond to the definition of FSMP and should rather be considered as a food supplement.

The Italian delegation asked the Committee to provide its views and all the delegations that intervened agreed that the product in question does not correspond to the definition of FSMP.