



EUROPEAN COMMISSION

HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

sante.ddg2.g.5(2016)6727863

**SUMMARY REPORT OF THE  
STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED  
HELD IN BRUSSELS ON 10 OCTOBER 2016  
(Section General Food Law)**

*CIRCABC Link:* <https://circabc.europa.eu/w/browse/b19cf203-cc0c-4d59-a616-1ac2c10a6739>

- A.01 Exchange of views of the Committee on the Greek notification on the obligatory indication of the origin of milk and dairy products (Notification under Article 45 of Regulation (EU) No 1169/2011).**
- A.02 Exchange of views of the Committee on the Greek notification on origin labelling of rabbit meat (Notification under Article 45 of Regulation (EU) No 1169/2011).**

**Points A.01-A.02**

The Greek delegation provided a presentation of their draft texts and their justifications.

With regard to the draft on origin indication of milk and milk products, it has been explained that the rules would apply for pre-packed milk and milk used as an ingredient in certain dairy products, when they are pre-packed. The draft law foresees a mutual recognition clause and would apply until 30 months after its publication. Furthermore, the Greek authorities explained that three months before the end of the validity period, there would be a specific evaluation of the effectiveness of the measure which will be communicated to the Commission.

With regard to the draft measure on origin indication of rabbit meat, the Greek delegation explained that mandatory indication of the "country of slaughter" required by its provisions is not limited in time and would apply for prepacked and non-prepacked rabbit meat. It has also been clarified that foods lawfully produced or marketed in another Member State of the European Union would not be subject to these labelling requirements.

During the subsequent discussion, a number of Member States provided their views on the notified measures. Some of them strongly criticised the lack of a coherent

treatment of the national notifications in the field of voluntary and mandatory origin labelling.

- A.03 Exchange of views of the Committee on a notification by Greece (2016/0292/GR) on the Supreme Chemical Council of the State Decision No 47/2016 entitled "Replacement of the title of Chapter IX of the Hellenic Food and Beverages Code (Government Gazette 788/B/31.12.1987) as in force, and insertion of Article 87a entitled 'Royal jelly' into said Chapter of the Hellenic Food and Beverages Code" - country of collection for prepacked royal jelly (Notification under Article 45 of Regulation (EU) No 1169/2011).**

This item was withdrawn from the agenda.

- A.04 Exchange of views of the Committee on a Working document prepared by the Commission services for consultation of Member States on four health claims related to "Low-fat fermented milk with a combination of fructo-oligosaccharides and live *Lactobacillus rhamnosus* GG (ATCC 53103), *Streptococcus thermophilus* (Z57) and *Lactobacillus bulgaricus* (LB2), and defence against reactivation of Herpes simplex virus in the orolabial epithelia" (Question EFSA No Q-2015-00488); "FHI LFC24, a bovine milk-derived casein hydrolysate, and a reduction of post-prandial blood glucose responses" (Question EFSA No Q-2015-00755); "*Lactobacillus plantarum* 299v and an increase of non-haem iron absorption" (Question EFSA No Q-2015-00696) and "V0137 and a reduced loss of cognitive function" (Question EFSA No Q-2016-00071) pursuant to Regulation (EC) No 1924/2006 (Art. 13(5) of Regulation (EC) No 1924/2006).**

Member States were consulted on four health claims submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, for which the European Food Safety Authority (EFSA) published its opinions in July/August 2016. More specifically, the applications subject to this working document related to the effects of:

- Low-fat fermented milk with a combination of fructo-oligosaccharides and live *Lactobacillus rhamnosus* GG (ATCC 53103), *Streptococcus thermophilus* (Z57) and *Lactobacillus bulgaricus* (LB2), and defence against reactivation of Herpes simplex virus in the orolabial epithelia
- FHI LFC24, a bovine milk-derived casein hydrolysate, and a reduction of post-prandial blood glucose responses
- *Lactobacillus plantarum* 299v and an increase of non-haem iron absorption
- V0137 and 'a reduced loss of cognitive function'

The Commission presented the working document and the health claim therein. No comments were raised by the delegations. The matter will be referred for further discussion at experts' level.

- A.05 Exchange of views of the Committee on a Working document prepared by the Commission services for consultation of Member States on one health claim related to "Iron and contribution to the normal function of the immune system"**

**(Question EFSA No Q-2008-146) pursuant to Regulation (EC) No 1924/2006 (Art. 14(1)(b) of Regulation (EC) No 1924/2006).**

As provided for in Article 17(1) of Regulation (EC) No 1924/2006, Member States were consulted on one health claim 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 application subject to this working document related to the effect of: "Iron and contribution to the normal function of the immune system".

The Commission presented the working document and the health claim therein and confirmed to the delegations that this health claim will also be subject to the discussions currently taking place on children claims. Three delegations reiterated their request to the Commission to set reference intake values for children, in addition to the reference intakes set out in Annex XIII of Regulation (EU) No 1169/2011.

The comments expressed during that discussion will be taken into account by the Commission. The matter will be referred for further discussion at expert's level.

**A.06 Exchange of views of the Committee on a notification by the Czech Republic (2016/257/CZ) of a draft Implementing Decree on food supplements and the composition of foodstuffs.**

On 3 June 2016, the Czech authorities notified via the TRIS system a draft Implementing Decree on food supplements and the composition of foodstuffs. On 21 September 2016, the Czech authorities notified the relevant provisions of the draft measure under Article 12 of Regulation (EC) No 1925/2006 and under Article 45 of Regulation (EU) No 1169/2011, following a request by the Commission and according to the notification procedures laid down by these pieces of legislation.

The Czech delegation presented the draft measure that provides *inter alia* for a list of substances other than vitamins and minerals that are authorised for use in food supplements under certain conditions of use, and a list of substances other than vitamins and minerals that are prohibited for use in food production. The Czech delegation explained that the draft measure lays down warning statements for certain substances and that these were considered to be necessary for the protection of public health and consumer health.

During the exchange of views, certain delegations sought clarifications with regard to the application of the mutual recognition principle as the draft measure does not include a provision laying down a mutual recognition clause. Further clarifications were sought regarding the reasons for the inclusion of certain substances in the list of prohibited substances of the notified draft measure, such as melatonin and lactulose that are permitted for use in other Member States under certain conditions of use. Further clarifications were sought by some delegations on the inclusion of certain substances in the positive list of the notified draft measure that are currently not permitted for use in foods in other Member States. A delegation commented on the inclusion of warning statements for certain substances and was of the view that such statements should not be permitted on foods as a general principle. The Czech delegation informed the Committee that replies to these questions would be sent within a week.

Some Member States took the opportunity to underline the need to harmonise the use of other substances in foods and food supplements. A delegation proposed the use of the procedure under Article 8 of Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods, to lay down harmonised conditions of use for the use of substances other than vitamins and minerals in foods. The Commission took note of the delegations' comments and reminded the Czech authorities to send the requested clarifications as soon as possible so as to enable the Commission to assess the relevant provisions within the deadline of 3 months and that of 6 months under the notification procedures of Regulation (EU) No 1169/2011 and of Regulation (EC) No 1925/2006, respectively.

In accordance with the procedure laid down in Article 12 of Regulation (EC) No 1925/2006 and that laid down in Article 45 of Regulation (EU) No 1169/2011, the Commission will express its opinion regarding this notification taking into consideration this exchange of views.

**A.07 Exchange of views of the Committee on the request by the Danish authorities to adopt an interpretation decision pursuant to Article 3 of Regulation (EU) No 609/2013 on a product placed on the market in Denmark as food for special medical purposes.**

At the request of Denmark, 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 tablet containing alpha-lipoic acid (thioctic acid), placed on the market in Denmark as FSMP for the dietary management of lack of alpha-lipoic acid in diabetic neuropathy. According to the food business operator, the product meets the nutritional requirements of the target group and, by acting against oxidative stress, helps to reduce the discomfort of patients suffering from diabetic neuropathy. For this reason, the operator considers that the product corresponds to the definition of FSMP currently laid down in Article 2(2)(g) 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.

The Danish 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 for the first time an interpretation decision pursuant to Article 3 of Regulation (EU) No 609/2013.

The Commission opened the floor to get Member States' views on the product and all the delegations that intervened raised doubts on its classification as FSMP. Member States referred to the definition of FSMP 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*". Member States noted that similar products are placed on the market in their territory as food supplements, so that patients suffering from diabetic

neuropathy can satisfy their specific nutritional requirements (if these exist) by modifying the normal diet through consumption of the food supplements. The Commission agreed with Member States and stressed that a key element of the definition of FSMP is indeed the fact that 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.

In the context of this discussion, one Member State additionally noted that products presented for the treatment of neuropathy are sold on its territory as medicinal products.

Several delegations showed great interest in the potential of Article 3 of Regulation (EU) No 609/2013 to address the reported increasing number of products incorrectly placed on the market as FSMP in their territory. Additional examples of products that could be subject of such interpretation decisions were mentioned and the Commission was asked to clarify how Article 3 would concretely apply, given that no details are provided in the legislation.

The Commission first recalled the discussions on the classification of FSMPs that already took place in previous Standing Committee meetings, as well in a dedicated Working Group on 14 March 2014 and in an Expert Group on Regulation (EU) No 609/2013 on 22 June 2015 (where a first reflection took place on the practical procedural elements related to the adoption of an Article 3 decision).

The Commission then clarified with the Committee that the ultimate decision to act pursuant to Article 3 of Regulation (EU) No 609/2013 remains entirely within the Commission's discretion and that this Article is not intended to replace the presently applicable 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). Article 3 empowers the Commission to take decisions in order to ensure the uniform implementation of Regulation (EU) No 609/2013. Hence, the Commission considers that 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. As it was discussed in the Expert Group of 22 June 2015, potential candidates for such decisions should be brought to the Commission's attention by Member States based on their competence for the enforcement of EU food law and preliminary exchanges of views should take place between the Commission and Member States to inform the Commission's consideration of the case (e.g. by adding the item to the agenda of a Standing Committee meeting). If the Commission intends to seek the advice of the European Food Safety Authority on a specific product, dossiers should be prepared by food business operators following the *Scientific and Technical guidance on foods for special medical purposes in the context of Article 3 of Regulation (EU) No 609/2013* adopted by the Authority in 2015.

The Commission noted that, in the specific case presented by Denmark, no disagreement exists among Member States on the product's classification, so that

issues related to the uniform implementation of Regulation (EU) No 609/2013 are not likely to arise. In light of the above, the Commission concluded that, on the basis of the information available, it does not find it necessary to adopt an interpretation decision pursuant to Article 3 of Regulation (EU) No 609/2013.

**A.08 Exchange of views of the Committee on the health claims related to caffeine following the objection of the European Parliament on 7 July 2016.**

The Commission informed the Member States on the European Parliament's (EP) objection, of 7<sup>th</sup> July 2016, on the draft Regulation authorising four health claims on caffeine and rejecting one, which received the favourable opinion of the Committee on 12 April 2016. It clarified to the Member States that following this objection the Commission could not adopt the measure that had been submitted to the Committee in April.

The Commission noted that the main focus of the EP's Resolution was related to an objection to energy drinks, which have a sugar and caffeine content, and their abuse by children and adolescents. In that context, in its resolution, the EP called on the Member States to adopt measures restricting the marketing of energy drinks to children and adolescents.

The discussion was mainly focused around the health claim which raises safety concerns, namely the health claim on the effect of caffeine on perceived exertion/effort during exercise. The Commission recalled that the intention of the Committee was to not authorise it on the basis of the latest EFSA opinion on the safety of caffeine intake, which recommended a consumption of 3 mg/kg body weight as a safe caffeine intake, while in order to obtain the claimed effect, caffeine should be consumed at doses of 4 mg/kg body weight.

The delegations were invited to consider whether, pending a legal solution, the above-mentioned health claim on caffeine should remain on the EU market, despite the transitional measures foreseen for health claims remaining on hold. Based on the above safety elements, the Commission expressed its view that this claim should not be used on foods present on the EU market, pending a final decision on the matter and that a common approach should be adopted amongst Member States.

Two delegations shared the concerns of the EP on the use of these claims on energy drinks and considered that the warnings proposed in the restrictions of use in the draft Regulation were probably not sufficiently addressing that issue after all. However, on the other hand, a third delegation highlighted the fact that the energy drinks' industry has a voluntary Code of Practice for the marketing and labelling of energy drinks. There was a general agreement among the Member States on the difficulty to implement the on-hold list with one delegation noting that health claims which were on-hold have been increasingly used by food business operators on the market. Following a question raised by a delegation regarding the applicable conditions of use of the caffeine on hold claims, the Commission reminded the Committee of the transitional measures under which on-hold health claims may be used.

The Commission informed delegations that it will further reflect on this matter and that in all cases, the issue will be referred for further discussion at experts' level.

**A.09 Exchange of views of the Committee on the Finnish notification on the indication of the country of origin of milk and milk and meat used as ingredient (Notification under Article 45 of Regulation (EU) No 1169/2011).**

The Finnish delegation presented the draft measure introducing the indication of country of origin of milk as well as of milk and meat used as an ingredient of pre-packed foods intended for a final consumer or mass caterers. It has been clarified that the provisions will not apply on foods lawfully produced in other Member States of the European Union and that they will be limited in time. The Finnish authorities also informed that the final text is likely to foresee some changes following the comments of the stakeholders which have been addressed to the Finnish authorities recently.

Furthermore, it has been clarified that there is a strong consumers demand in Finland for more comprehensive information on the origin of the foods in question. In this regard, a reference to different surveys has been made. It has also been explained that the situation with regard to animals diseases and zones in the Finnish food chain is good and the need to use antimicrobials medicines for animals is quite minimal.

The debate on the notified draft was combined with the national notifications presented under points A.01 and A02.

**B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation refusing to authorise a health claim made on foods and referring to the reduction of disease risk.**

This draft Commission Regulation was submitted to the Standing Committee in accordance with Article 17(3) of Regulation (EC) No 1924/2006. It aims at refusing to authorise the use of one health claim made on foods and referring to the reduction of disease risk, pursuant to Article 14(1)(a) of Regulation (EC) No 1924/2006. More specifically, the application subject to this draft measure relates to the effects of Anxiofit-1 and reduction of subthreshold and mild anxiety, which is a risk factor in the development of anxiety disorders and depression.

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 claim therein.

There were no comments or observations by the delegations.

**Vote taken:** Favourable opinion.

**B.02 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) amending Regulation (EC) No 178/2002 of the**

**European Parliament and of the Council as regards the names and the areas of competence of the scientific panels of the European Food Safety Authority.**

The Commission presented the item: the change of three Panels' names is proposed following a request from EFSA; the objective is to better balance the workload of EFSA's Panels and thus to ensure a more effective and efficient functioning of EFSA. The timing of the change of Panels is in line with the current renewal of the ANS and CEF Panels whose new term of office will start on 1 July 2017 (till 30 June 2018). The draft Regulation should be applied as from 1 July 2018 allowing all EFSA Panels to start their mandate on the same date. The Commission confirmed that the alphabetical listing of the Panels' names in Article 28(4) as proposed in the draft corresponds to a consolidated version of the Regulation including previous changes of the Panels' names.

**Vote taken:** Favourable opinion.