



EUROPEAN COMMISSION

HEALTH & CONSUMERS DIRECTORATE-GENERAL

**STANDING COMMITTEE ON THE FOOD CHAIN AND ANIMAL HEALTH
SECTION ON GENERAL FOOD LAW**

Summary Record of Meeting of 6 December 2010

**Chairman: Mr Basil Mathioudakis (for items 1 to 6)
Ms Chantal Bruetschy (for item 7 to 9)**

Member States absent and represented:

For items 1 to 5: 2

For item 6 to 7: 3

For item 8: 5

For item 9: 8

- 1. Exchange of views 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. (SANCO/13182/2010) (11th batch, Art. 13(5) of Regulation (EC) N° 1924/2006) (Regulatory procedure with scrutiny of the European Parliament and of the Council). (CA)**

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

The applications were based on newly developed scientific evidence and for two of them the applicants were requesting the protection of proprietary data.

More particularly, one application related to the effects of *Synbio*, containing two probiotic bacterial strains, on the maintenance and improvement of intestinal well-being. One application related to the effects of silymarin BIO-C®, an extract of milk thistle seeds, on the increase of production of breast milk after delivery. The third application related to the effects of another probiotic strain, present in the fermented milk product Yakult®, on the maintenance of the upper respiratory tract defence by helping to support immune functions.

The Commission presented the health claims listed in the draft Regulation and informed that comments were submitted pursuant to Article 16(6) of the Regulation (EC) No 1924/2006.

One delegation signalled that claims related to certain foods may also be subject to the procedure for authorisation of Article 13(1) health claims. The Commission recalled first, that the two types of claims were submitted through different procedures and should therefore be treated separately and second, that the authorisation of health claims is an ongoing process allowing for the revision of the lists of permitted claims and their conditions of use accordingly.

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

2. Exchange of views on a Draft Commission Regulation on the authorisation and refusal of authorisation of certain health claims made on foods and referring to the reduction of disease risk (SANCO/13183/2010) (11th batch, Art. 14 of Regulation (EC) N° 1924/2006) (Regulatory procedure with scrutiny of the European Parliament and of the Council). (CA)

The draft Commission Regulation was submitted to the Standing Committee in accordance with Article 17(1) of Regulation (EC) No 1924/2006. It intends to authorise two health claims provided for in Article 14(1)(a) and referring to the reduction of two risk factors, namely tooth demineralisation and plaque acids, in the development of dental caries.

The Commission noted that the title of the draft measure submitted to the Committee is not in line with the content of the measure and that it should read: *"Draft Commission Regulation authorising certain health claims made on foods and referring to the reduction of disease risk"*.

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

3. Exchange of views on the addition of a new mixture of oligosaccharides to infant and follow-on formulae

Following information from an infant formulae manufacturer to the competent authorities in certain Member States of its intention to place on the market a product with a new ingredient, an exchange of views was requested by some Member States on the procedure that should apply to such notifications.

As it appeared that clarification would be desirable on the procedure that applied in such cases, the Commission explained that Directive 2006/141/EC on infant formulae and follow-on formulae provides the basis for the procedure. Indeed, Articles 4 to 6 of the Directive apply to ingredients, used in infant formulae and follow-on formulae that were not specified in the Directive. In addition, in the case of infant formulae, Article 9 obliges food business operators to inform the competent authorities when they place an infant formula on the market. This is not a prior authorisation procedure for the marketing of a product. When a food business operator places a product with a new ingredient on the market, the legislation requires that a dossier substantiating that the ingredient is safe and suitable for the intended purpose, must be available. The Member State may request to evaluate that dossier if they wish to do so. The Commission noted that when a formula with a new ingredient is placed on the market in one Member State then the rules of mutual recognition would apply. A Member State could only restrict the marketing of a product if they had justified grounds to do so.

Some Member States indicated that they would prefer a centralised authorisation procedure for a new ingredient, based on the advice of the European Food Safety Authority with regard to the safety and suitability of the ingredient. It was noted by the Chair that such proposal could be assessed in the context of the future review of the legislation on dietetic foods.

Finally, it was suggested that with respect to the existing procedure, an exchange of information between Member States on notifications received would facilitate the consideration of such notifications by the competent authorities.

4. Exchange of views on a Danish notification under Article 12 of Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods (YA, AK)

On 6 July 2010 the Danish authorities notified under Regulation (EC) No 1925/2006 a draft Executive Order on the addition to food of certain substances, other than vitamins and minerals, with a nutritional or physiological purpose.

The Danish delegation presented their draft measure that would allow food business operators to place on the market foods, including food supplements, containing the substances listed therein, and complying with the conditions of use set for each of them, without having to undergo prior authorisation, which is the current practice.

The list comprises the substances and the uses for which there have been applications and that have been assessed. Thus, substances not listed and/or other uses would be submitted to an authorisation procedure and a risk assessment shall be carried out, while substances allowed in other Member States could be placed on the market after a notification of the competent authorities by the food business operator.

The Danish delegation also explained that there are mistakes in the English translation of the draft measure; in particular, the statement "not allowed" should be replaced by "not yet allowed" or "to be determined".

During the exchange of views some delegations expressed their concerns regarding the potential creation of obstacles to the marketing in Denmark of products legally placed on the market in another Member State. Some delegations sought clarifications concerning the scope of the notified measure in relation to substances, such as lycopene, that have been granted authorisation under Regulation (EC) 258/97 on the authorisation of novel foods and novel food ingredients. Clarification was also sought on whether the levels for those substances listed in Appendix I included addition of the substance from all sources, including from its use as an additive.

Some delegations expressed the view that a harmonised approach at EU level on the addition to food of substances other than vitamins and minerals would be desirable.

In reply to these comments, the Danish delegation clarified that the draft Executive Order would apply without prejudice to other specific legislations, such as the novel food, dietetic foods or the additives ones. It also confirmed that Denmark will submit a revised notified draft taking into account the comments raised by the Committee.

The Commission will express an opinion on the revised draft to be submitted by Denmark.

5. Exchange of views and possible opinion 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 (SANCO/12561/2010) (8th batch, Art. 13(5) of Regulation (EC) N° 1924/2006) (Regulatory procedure with scrutiny of the European Parliament and of the Council). (CA)

The draft Commission Regulation, already presented to the Standing Committee on 11 October 2010, aims at adopting a decision, in accordance with Article 18(5) of Regulation (EC) No 1924/2006, refusing to authorise the use of seven health claims provided for in Article 13(5) of that Regulation. The applications were based on newly developed scientific evidence and, for some of them, the applicants were requesting the protection of proprietary data, as provided for in Article 13(5) of that Regulation.

The Commission presented the draft and the health claims therein, including the EFSA opinions, the comments submitted pursuant to Article 16(6) of the Regulation (EC) No 1924/2006 and the EFSA responses to those comments. An exchange of views took place.

Regarding the authorisation of the health claim "*Ethanol-water extract of Caralluma fibriata (Slimaluma®) helps to control hunger/appetite*", EFSA considered that a reduction of appetite leading to a reduction in subsequent energy intake, might be a beneficial physiological effect. However, in relation to this specific application, EFSA considered that the demonstrated reduction in energy intake was not significant, and, therefore, considered that a beneficial effect had not been demonstrated.

The Committee discussed whether, for a claim referring to the reduction or control of sense of hunger/appetite, it is sufficient to demonstrate only the reduction/control of sense of hunger/appetite or it should also be demonstrated that such reduction/control should be accompanied by a reduction in subsequent energy intake as considered by EFSA. Two delegations questioned the EFSA's reasoning and noted that the reduction in the sense of hunger/appetite alone could fall under the scope of the Regulation.

Nevertheless, the majority of delegations shared EFSA's reasoning.

Following an editorial change in the submitted draft, the Committee delivered a favourable opinion by unanimity.

6. Exchange of views and possible opinion on a Draft Commission Regulation on the authorisation and refusal of authorisation of certain health claims made on foods and referring to children's development and health (SANCO/13017/2010) (10th batch, Art. 14 of Regulation (EC) N° 1924/2006) (Regulatory procedure with scrutiny of the European Parliament and of the Council). (CA)

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 four health claims and rejecting three health claims provided for in Article 14(1)(b) of Regulation (EC) No 1924/2006, following nine different applications. The health claims concerned relate to the effects of docosahexaenoic acid (DHA) and α -linolenic acid (ALA) on visual, brain and eye development of children.

A previous draft measure related to the same applications was submitted by the Commission to the Standing Committee for vote on 7 December 2009 but it was then agreed that further discussions were necessary on technical aspects. Following lengthy discussions with Member States and stakeholders and taking into account the additional advice from EFSA with regard to the conditions of use of the claims and their target populations, a new draft was prepared.

Regarding the claim on ALA and brain development of children one delegation raised additional concerns with regard to the conditions of use of the claim, and the Committee agreed not to include it in the draft Regulation at this stage in order to clarify the issue. This claim will be included in a further draft measure that will be submitted to the Standing Committee at a future meeting.

Regarding the claim on DHA and visual development of infants up to 12 months, consideration was given to extending the target population of the claim to children of all ages. Nevertheless, following discussions on technical aspects and concerns raised with regard to the conditions of use, the Committee decided to authorise the health claim as proposed by the applicant.

Regarding the claims on DHA and brain development submitted for rejection, it was underlined that the advice currently available did not allow the risk managers to set appropriate conditions of use.

Three delegations expressed the view that allowing the use of health claims on foods intended for infants and young children, and more specifically on follow-on formulae, could make such products more attractive for mothers and thus could interfere with the promotion of breast feeding and questioned their authorisation. It was recalled that issues relating to the marketing of products intended for the feeding of infants are covered in relevant specific EU legislation.

Following the consequent changes in the submitted draft the Committee delivered a favourable opinion by qualified majority (in favour: 305 votes; abstention: 33 votes; against: 7 votes).

7. Exchange of views and possible opinion on a Draft COMMISSION DECISION authorising the placing on the market of a mycelial extract from *Lentinula edodes* (Shiitake mushroom) as a novel food ingredient under Regulation (EC) N° 258/97 of the European Parliament and of the Council (SANCO/12603/2010) (Right of scrutiny of the European Parliament) (SANCO E6)

It was agreed to edit the specifications in Annex I corresponding to the format provided by table 1 of the EFSA opinion¹. Annex II was amended, in particular for soft drinks the maximum level to be used was reduced to 0.5 mL/100 mL as Member States expect that higher amounts of soft drinks will be consumed than considered by EFSA.

The draft Decisions received a favourable opinion by unanimity (345 votes in favour)

8. Exchange of views and possible opinion on a Draft COMMISSION DECISION authorising the placing on the market of a Chitin-glucan from *Aspergillus niger* as a novel food ingredient under Regulation (EC) N° 258/97 of the European Parliament and of the Council (SANCO/12602/2010) (Right of scrutiny of the European Parliament) (SANCO E6)

The draft Decisions received a favourable opinion by qualified majority (316 votes in favour; 29 votes abstention)

9. Exchange of views and possible opinion on a Draft COMMISSION DECISION authorising the placing on the market of a Sardine (*Sardinops sagax*) peptide product as a novel food ingredient under Regulation (EC) N° 258/97 of the European Parliament and of the Council (SANCO/12601/2010) (Right of scrutiny of the European Parliament) (SANCO E6)

As a result of the discussions, some editorial changes in Annexes I and II were agreed. There was concern that in the designation of foods the word 'Sardine' was reserved to the species *Sardina pilchardus*. Therefore it was agreed that the designation in the list of ingredients will be 'fish (*Sardinops sagax*) peptides'

The draft Decision received a favourable opinion by qualified Majority (295 votes in favour; 21 votes against; 29 votes abstention)

¹ EFSA Journal 2010; 8(7): 1685