



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 22 February 2010**

**Chairman: Mr Basil Mathioudakis**

**Member State absent and represented: 1 (for item 3) 5 (for item 4)**

**Member State absent and not represented: 2 (for item 3) 1 (for item 4)**

**1. Exchange of views on a notification (Directive 2000/13/EC) by Italy of a draft Decree governing the use of substances other than vitamins and minerals, in particular with respect to additional labelling of warnings.**

On 22 January 2010 the Italian authorities submitted complementary information in support of the notified draft Regulation governing the use of substances other than vitamins and minerals in food supplements, in particular with respect to additional labelling requirements under the form of warnings (TRIS message reference 2010-00176).

The draft was first presented at the Committee meeting of 26 January 2010 and briefly discussed in the meeting of the working group on nutrition and health claims of 15 February 2010.

The Commission explained that the notified draft provides for additional mandatory labelling requirements to specific food supplements. In particular, it lays down labelling requirements for warnings and mandatory indications of nutritional or physiological effects attributed to specific food supplements containing herbal extracts and other substances with nutritional or physiological effect.

The notified draft provides for the indication of warnings with respect to nine substances listed in Annexes (Cimicifuga racemosa Nutt, Citrus aurantium L., Ginkgo Biloba L., Hypericum Perforatum L., Mixtures of Amino acids, Ramfied amino acids, Bioflavonoids, Creatine, Monascus purpureus (red yeast rice) monacolin).

During the exchange of views, the Member States which took part to the discussion did not object in principle to the warnings provided that they are intended to ensure that consumers are correctly informed, or that there are sufficient scientific justifications.

With respect to mandatory indications of nutritional or physiological effects, most of the Member States expressed their concerns about the interaction of the notified draft with other EU legislations, in particular with Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements and Regulation (EC) No 1924/2006 on nutrition and health claims made on foods. Some Member States emphasised that indication of nutritional or physiological effects is not required under Directive 2002/46/EC for food supplements containing vitamins or minerals. Furthermore, it was stressed that the notified draft providing for mandatory indication of the physiological or nutritional effects would result in such mandatory indications falling outside the scope of Regulation (EC) No 1924/2006 as the core principle of that Regulation is that nutrition and health claims are made on a voluntary basis.

Therefore, whether Member States are still allowed to introduce national measures imposing mandatory statements which would amount to claims is questionable as this would circumvent the rules laid down in Regulation (EC) No 1924/2006.

The Commission will express an opinion regarding this notification by 23 April, taking into consideration this exchange of views.

## **2. Exchange of views on the first series of EFSA opinions on Article 13 claims.**

The Commission presented a working document outlining an envisaged decision flow chart on Article 13 claims assessed by EFSA. The Commission informed the Member States that the first series of EFSA opinions received on 1st of October 2009 had been assessed against the decision tree and that subsequent series of opinions from EFSA will be subject to similar assessments. It followed from the assessment of the first series of opinions that a number of health claims were not substantiated, while for a substantial number of health claims the presented evidence or information had been insufficient to allow EFSA to draw any conclusions on the claimed effects.

In view of this, the Commission considered that it would be appropriate to set up procedures that would allow a quick completion of the assessment of the claims for which according to the Commission assessment no conclusion was drawn.

Given the late circulation of the document and the complexity of the issues, Member States expressed only preliminary views.

While one Member State expressed its general disagreement with the progressive adoption of the Union list of approved claims, all the delegations which took part in the discussion welcomed the document, as it provides clarity on the way forward.

Most of them were in principle in agreement with the general approach outlined by the Commission, and on the possibility to allow for missing evidence or data to be provided by the operators. However, a number of delegations expressed reservations or concerns on the possibility to question the risk assessment where EFSA did not take certain type of evidence into account.

Regarding the procedure, it was recalled that, given the need to have a quick completion of the assessment of the claims concerned, an active involvement of the national authorities in checking the validity of the submissions would be necessary.

Finally, as the Commission raised the issue of the different transition provisions applicable respectively to Article 13(1) a), and 13(1) b) and c) claims, Member States confirmed that submission of Article 13(1) b) and c) claims in accordance with Article 13(2) was considered sufficient in terms of observing the transition regime referred to in Article 28(6) (a).

Delegations were encouraged to submit written comments with a view to continue the discussion, including on the procedural issues, in the working group on claims.

**3. Exchange of views and possible opinion on a Draft Commission Decision authorising the placing on the market of puree and concentrate of the fruits of *Morinda citrifolia* as a novel food ingredient under Regulation (EC) N° 258/97 of the European Parliament and of the Council (SANCO/5754/2009 Rev. 3) (Article 7 of Regulation (EC) N° 258/97) (Right of scrutiny of the European Parliament).**

The draft Decision submitted to the Committee aims at authorizing the use of *Morinda citrifolia* (Noni) fruit puree and concentrate as novel food ingredients under the conditions specified in its Annexes, following the EFSA conclusion, in its opinion of 13 March 2009, that these products are safe for the general population.

During the exchange of views, one Member State indicated that it would put in place a post market monitoring, because EFSA in its report had considered that case reports might indicate that some individuals have a particular sensitivity for hepatotoxic effects to noni products. For the same reason, one other Member State requested the deletion of a number of the food categories in Annex II of the draft Decision.

The delegation of the United Kingdom, noting that the upper daily limit for the fruit puree in food supplements was high, questioned the consistency of such a dose with the definition of food supplement in Directive 2002/46/EC, which refers to "small measured quantities". The UK therefore requested that the Commission seek clarification from national experts and from its Legal Service on the interpretation of this definition. The chairman pointed out that the interpretation of definition of food supplements was for the Member State's controlling authorities on a case by case basis and had not given rise to problems.

Some editorial amendments were agreed; in particular the maximum use values of *Morinda* puree and concentrate in Annex II were rounded to full g of *Morinda* puree or concentrate per 100g of final product.

The Standing Committee delivered a favourable opinion by qualified majority (in favour: 305 votes; against: 17 votes; abstention: 12 votes; absent 11 votes).

**4. Exchange of views and possible opinion on a Draft Commission Decision concerning the draft Decree notified by Italy setting out standards governing the labelling of shelf-stable milk, UHT milk, micro-filtered pasteurised milk and high-temperature pasteurised milk, as well as milk products**

**(SANCO/10176/2010) (Article 19 of Directive 2000/13/EC of the European Parliament and of the Council) (Right of scrutiny of the European Parliament).**

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

On 25 August 2009, the Italian authorities notified under Directive 2000/13/EC relating to the labelling, presentation and advertising of foodstuffs<sup>1</sup> a draft Decree setting out standards governing the labelling of shelf-stable milk, UHT milk, micro-filtered pasteurised milk and high-temperature pasteurised milk, as well as milk products.

The notified Decree provides *inter alia* obligation to indicate the place of origin of the milk on the labels of sterilised shelf-stable milk, UHT milk, micro-filtered pasteurised milk and high-temperature pasteurised milk (Article 2), milk products (Article 3(1) and 3(3)), and cheeses obtained from curd (Article 4).

The Italian authorities argued that the notified measure is necessary to define and regulate the traceability system for sterilised shelf-stable milk, UHT milk, micro-filtered pasteurised milk and high-temperature pasteurised milk and milk products. They also state that such measure is necessary to regulate the labelling of the foods listed in Article 1 thereof in order to ensure that the interests of the consumer are protected to the greatest extent.

Some delegations expressed support for the Italian measure which they consider justified for providing consumers with appropriate and complete information.

One delegation expressed the view that the issue of origin should be better addressed in the context of the Commission proposal for a Regulation on the provision of food information to consumers as that would allow a common approach at EU level.

The Commission pointed out the fact that national initiatives on origin are more and more frequent, and thus it is preferable to wait for the outcome of the ongoing discussions in the European Parliament and the Council on the proposal for a Regulation on the provision of food information to consumers.

The Committee delivered a favourable opinion by qualified majority (in favour: 258 votes; against: 44 votes; abstention: 39 votes; absent: 4 votes).

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<sup>1</sup> OJ L 109, 6.5.2000, p. 29.