STANDING COMMITTEE ON THE FOOD CHAIN AND ANIMAL HEALTH
SECTION ON GENERAL FOOD LAW
Summary Record of Meeting of 27 April 2009

Chairman: Mr Basil Mathioudakis

Member State absent and represented: 1

1. Exchange of views on a draft Commission Regulation refusing to authorise certain health claims made on food, other than those referring to the reduction of disease risk and to children's development and health.

   The draft Commission Regulation was submitted to the Standing Committee, in accordance with Article 18 (5) of Regulation N° 1924/2006, and concerned one application for authorisation of a health claim, based on newly developed scientific evidence and including a request for the protection of proprietary data, as provided for in Article 13(5) of that Regulation.

   The draft Regulation will be subject to further discussions 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 food and referring to the reduction of disease risk and to children's development and health.

   The draft Regulation was submitted to the Standing Committee, in accordance with Article 17 (1) of Regulation N° 1924/2006, and concerned four applications for authorization of use of health claims provided for in Article 14(1) of that Regulation.

   The draft Regulation will be subject to further discussions and put to the vote of the Committee in a future meeting.


   The Commission presented the draft Regulation amending Regulation (EC) No 353/2008, underlining the two main amendments to be considered. The new Article 7a aims at clarifying the role of national authorities in the control of the validity of applications, regarding the scope as referred to in Articles 15 and 18 of Regulation (EC) No 1924/2006 and regarding the data to be provided as referred to in Article 15(3) of the above-mentioned Regulation.
The Commission noted that the new Article 7a clarifies the interpretation of the primary regulation and therefore does not impose as such any new obligation on the Member States.

The new Article 7b aims at clarifying the rules applicable to the requests for withdrawals of applications for authorisation of health claims, following the conclusions of the Committee at its meeting on 20 February 2009. The Commission informed the delegations that some editorial changes could be made.

The draft Regulation will be subject to further discussions and put to the vote of the Committee in a future meeting.

4. Exchange of views and possible opinion on a draft Commission Regulation concerning the authorisation and refusal of authorisation of certain health claims made on food and referring to the reduction of disease risk and to children's development and health (Right of scrutiny of the European Parliament).

The draft Regulation aims at adopting a decision, in accordance with Article 17(3) of Regulation (EC) No 1924/2006, authorizing and/or refusing to authorise the use of health claims provided for in Article 14(1) of that Regulation. The draft Regulation concerns two health claims for authorisation and fourteen for rejection; a draft was first presented at the Committee meeting of 20 February 2009.

After a new exchange of views, the following conclusion was drawn on a particular issue that has been considered.

The Commission presented the EFSA response dated 16 April on the advice requested from the Commission concerning a possible identification of a risk factor of the disease of caries. The EFSA identified dental plaque as a risk factor in the development of caries from the data contained in the dossier submitted by the applicant. The Member States supported the suggested wording referring to dental plaque as the risk factor.

Some Member States expressed the wish to require an additional statement on products bearing such claim, reflecting that tooth brushing remains important to prevent caries/ensure good mouth/dental hygiene. They noted that such statements were made sometimes voluntarily on products concerned.

It was however considered that such additional requirement on the labelling of chewing gums would be disproportionate.

The Committee delivered a favourable opinion by unanimity.

5. Exchange of views and possible opinion on a draft Commission Regulation refusing to authorise certain health claims made on food, other than those referring to the reduction of disease risk and to children's development and health (Right of scrutiny of the European Parliament).

The draft Regulation aims at adopting a decision, in accordance with Article 18 of Regulation (EC) No 1924/2006, refusing to authorise the use of health claims provided for in Article 13(5) of that Regulation. It is related to three applications for authorisation of health claims, based on newly developed scientific evidence and including a request for the protection of proprietary data.
After a new exchange of views, the following conclusion was drawn on a particular issue that has been considered.

Article 13(3) of Regulation (EC) No 1924/2006 allows health claims describing or referring to the reduction in the sense of hunger. Following an application for authorisation of the health claim "This product reduces the sense of hunger", EFSA estimated that even though the reduction in the sense of hunger was scientifically substantiated, the effect was not shown to be beneficial “in helping the regulation of energy intake”, as the reduction of energy intake shown by the study was not significant.

Therefore an exchange of views took place on the question whether, for a claim referring to the reduction in the sense of hunger, it is sufficient to demonstrate only the reduction of the sense of hunger or it is relevant to demonstrate that such reduction in the sense of hunger leads to a reduction in energy intake, insofar the consumers would normally expect this.

As different views were expressed by the delegations, it was concluded that the health claim concerned should not be included in the draft Regulation at this stage and that the case should be subject to further consideration.

Following the consequent changes 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 substances that may be added for specific nutritional purposes.**

The draft Regulation aims at amending the list of the authorised sources of substances that can be added to dietetic foods following a favourable opinion issued by EFSA. In addition, that Regulation would recast and consolidate Directive 2001/15/EC, which was amended several times since its adoption.

The exchange of views focused principally on the inclusion in the abovementioned list of boric acid and sodium borate as sources of boron. Several Member States expressed their opposition to such inclusion, arguing that boron has not been shown to be an essential nutrient and that, due to the overall exposure, boron intakes could exceed the Upper Limit (UL) established by EFSA.

It was recalled by the Commission that the safety of a substance was a basic criterion for permitting its use. Further, for dietetic foods, their composition should be such that the products are appropriate for the particular nutritional use intended. Therefore, business operators are responsible for complying with the relevant provisions and Member States should enforce and control them.

The Commission assured Member States that in the exercise of setting maximum amounts for vitamins and minerals which are added to foods including food supplements, which is ongoing, it will pay attention to the maximum amount of boron for which there is a narrow margin between the UL and the potential intakes in certain Member States.

The Committee delivered a favourable opinion by qualified majority (in favour: 277 votes; against: 68 votes).
Any other business.

**Nutrient profiles (requested by CZ)**

The Commission informed the MS that a draft Regulation is being currently discussed among the Commission services but was not in a position to provide more details.