SUMMARY REPORT OF THE
STANDING COMMITTEE ON THE FOOD CHAIN AND ANIMAL HEALTH
HELD IN BRUSSELS ON 04 OCTOBER 2013
(Section General Food Law)

Chairman: Mr Basil Mathioudakis

26 Member States were present. Bulgaria was absent but represented by Belgium, Malta was absent but represented by Ireland.

A.1 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 supplemental folate intake (Question No EFSA-Q-2013-00265) and the combination of artichoke leaf dry extract standardised in caffeoylquinic acids, monacolin K in red yeast rice, sugar-cane derived policosanols, OPC from French maritime pine bark, garlic dry extract standardised in allicin, d--tocopheryl hydrogen succinate, riboflavin and inositol hexanicotinate in Limicol® (Question No EFSA-Q-2012-00968) pursuant to Regulation (EC) No 1924/2006 (Art.14(1)(a) 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 of that Regulation, for which EFSA published its opinions on 26 July 2013. More specifically, the applications subject to this working document related to the effects of:

•Supplemental folate intake and reduced risk of neural tube defects (NTD);
•A combination of artichoke leaf dry extract standardised in caffeoylquinic acids, monacolin K in red yeast rice, sugar-cane derived policosanols, OPC from French maritime pine bark, garlic dry extract standardised in allicin, d--tocopheryl hydrogen succinate, riboflavin and inositol hexanicotinate in Limicol® and reduction of blood LDL cholesterol concentrations.

The Commission presented the working document and the health claims therein.

On the health claim on supplemental folate intake, two Member States expressed their concerns about the implications of the fact that the nutritional status of a nutrient is the risk factor of a disease.

The Commission noted the concerns expressed by Member States and underlined that Member States should be vigilant in the future during the validity checks, when receiving applications for authorisation of such health claims referring to reduction of risk factors for conditions that are not relevant for European
consumers and thus could be misleading.

One Member State expressed serious concerns about the role of all the substances present in Limicol® on the substantiation of the health claim and their link/synergy with the active substance (Monacolin K). Another Member State questioned the novel status of all these substances used in Limicol®.

Regarding the issue of side effects of lovastatin-containing products, the Commission reminded that an initiative is on-going between some of the Member States in order to examine this issue with the possibility to refer back to EFSA if needed.

The comments expressed by the delegations during that discussion will be taken into account by the Commission in finalising its decision, and the issue is referred for further discussions at experts' level.

**A.2 Exchange of views of the Committee on a Working document prepared by the Commission services for consultation of Member States on 3 health claims related to magnesium - (Question No EFSA- Q-2008-150), vitamin A - (Question No EFSA- Q-2008-160) and iron - (Question No EFSA- Q-2008-199), 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 three health claims provided for in Article 14 of that Regulation, for which EFSA published its opinions on 26 July 2013. More specifically, the applications subject to this working document related to the effects of:

- Magnesium and contribution to normal development of bones;
- Vitamin A and contribution to normal development and function of the immune system;
- Iron and contribution to normal cognitive development.

The Commission presented the working document and the health claims therein.

The Commission explained that the consideration of these health claims relating to 'mandatory nutrients' should be done closely with the on-going implementation of the new Regulation (EU) No 609/2013 on food for specific groups.

One Member State expressed its support on the authorisation of health claims on nutrients whose presence in a given food is required by the legislation (mandatory nutrients). However, raised some concerns on the wording under which these health claims should be authorised which, in any case, should not contradict with the provisions of Article 2, paragraph 1(a) (iii) of Directive 2000/13/EC.

The comments expressed during that discussion will be taken into account by the Commission in finalising its decision while the issue is referred for further discussions at experts' level.
The Commission presented the working document and the health claims therein.

As provided for in Article 18(4) of Regulation (EC) No 1924/2006 Member States were consulted on a health claims for which EFSA published its opinion on 26 July 2013. More specifically, the application subject to this working document related to the effects of “non-fermentable” carbohydrates (Nutriose®) and maintenance of tooth mineralisation by decreasing tooth demineralisation.

One Member State pointed out some inconsistencies to the wording and the conditions of use between this claim and the claim on reformulated acidic drinks. Another Member State underlined the similarities of the claim on “sugar replacers” and the claim on “non-fermentable” carbohydrates (Nutriose®) and expressed its doubts on the opportunity of authorising such a new health claim on “non-fermentable” carbohydrates.

In addition, Member States were also consulted on two health claim provided for in Article 13(5) of Regulation (EC) No 1924/2006, for which EFSA published its opinion on 26 July 2013. More specifically, the applications subject to this working document related to the effects of:

- Proanthocyanidins in Urell® and reduction of bacterial colonisation of the urinary tract by inhibition of the adhesion of P-fimbriated E. coli to uroepithelial cells;
- Preservation® and rapid recovery of cellular activities post stress.

The comments expressed during that discussion will be taken into account by the Commission in finalising its decision while the issue is referred for further discussions at experts' level.

Italy presented a document and a summary of this document expressing their concerns vis-à-vis the nutrition labelling scheme that the UK authorities have recommended on 19 June 2013. The UK labelling scheme is a colour coded nutritional scheme that attributes a colour, red, amber or green, to the content of energy, fat, saturates, sugars and salt. Article 35 of Regulation (EU) No 1169/2011 on food information to consumers allows such additional forms of expression and presentation of the nutrition information on top of mandatory nutrition information, provided such schemes comply with the criteria laid down in this Article. Italy underlined its potential negative impact on trade and consumer choice.
The voluntary character of the colour coded scheme was questioned. According to the Italian authorities, the scheme should have been notified under Directive 98/34/EC, and the red lights attributed to the level of energy or nutrients would constitute non-beneficial nutrition claims, which also would have to be notified under Directive 98/34/EC following recital (6) of Regulation (EC) No 1924/2006 on nutrition and health claims made on foods. Italy also claimed that the UK scheme would constitute a barrier to trade in breach of Article 34 of the Treaty on the Functioning of the European Union, and that the multiplication of similar systems would undermine the harmonisation efforts. In its written document, Italy also questioned the possibility to recommend such scheme before 13 December 2014, date at which the nutrition information shall comply with the new rules. It was also suggested that such recommendation would only be possible after the adoption of the related implementing acts by the Commission.

UK replied that they were confident that their scheme was compliant with the legislation. UK claimed that the colour coded scheme has been subject to public consultation, was based on scientific studies on its understanding by consumers and that companies were free to adopt it, for their entire product offer or for some categories of products only. So far, 31 companies have chosen to adopt it. The UK delegation underlined no action was taken against any producer not following the scheme. UK signalled that in accordance with recital 46 of the Regulation on food information to consumers such scheme should be considered as a nutrition declaration and not as individual nutrition claims. To a question about the use of the scheme by retailers, it was answered that a retailer committed to use the scheme would use it for its own product ranges.

Some Member States shared the concerns of Italy vis-à-vis the UK recommended scheme and some recalled their position in favour of a harmonised system. Several delegations requested the Commission’s views concerning in particular the procedural aspects.

The Commission reminded that the voluntary additional forms of presentation and expression of nutrition information was extensively discussed during the negotiations on the new Regulation concerning the provision of food information to consumers. Due to the lack of evidence across the Union on how the average consumer understands and uses such information, the co-legislators finally agreed to allow for different voluntary forms of expression and presentation to be developed (both by food business operators and Member States) on the basis of certain criteria established in the Regulation. The aim is to allow further developments in this area and to enable the Commission to prepare in the future a report on the use of such forms, their impact on the internal market and the advisability of further harmonisation.

Consequently, the development of additional forms of expression or presentation of the nutrition information is compatible with the system established in the relevant Union legislation as long as it complies with the criteria established therein.

The Commission services had considered the relevant provisions and concluded that following Article 54(3) of Regulation (EU) No 1169/2011 read together with
Recital 56, recommendations by Member States can also be made before 13 December 2014 in accordance with Article 35 of the Regulation. It was also clarified that the lack of the implementing acts referred to in Article 35.6 does not constitute an obstacle to the application of Article 35 since its application is not subject to the adoption of the implementing act in question. On the need to notify the scheme under Directive 98/34/EC, the Commission analysed that a) it does not constitute a de jure mandatory labelling, as no legislation imposes it and b) on the basis of the available information it cannot be considered as de facto mandatory labelling. It was also clarified that the commitment by food business operators to use the scheme was not a voluntary agreement where the Member State is a contracting party, another condition leading to the need to notify under Directive 98/34/EC. The Commission shared the view that recital 46 of Regulation (EU) No 1169/2011 was considering such scheme as nutritional information and not as non-beneficial nutrition claims having to be notified.

The Commission also clarified that point (g) of Article 35 about potential obstacle to the free movement of goods should be considered as a reference to Articles 34 to 36 of the Treaty on the Functioning of the European Union. To conclude, the Commission recalled that interpretation of EU law was the prerogative of the Court of Justice. The Commission also stated that it will be vigilant that the UK scheme does not hinder the intra-Union trade and invited the UK authorities to follow the development of the use of the scheme on the market in order to avoid the creation of obstacles to trade.

**B.1 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.**

The 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 12 health claims foreseen in Article 13(5) of that Regulation. The applications were based on newly developed scientific evidence and for some of them the applicants requested 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 and no comments were raised on the substance of the health claims.

*Vote taken:* unanimous in favour.

**B.2 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.**

The 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 6 health claims foreseen in Article 13(5) of that Regulation. The applications were based on newly developed scientific evidence and for some of them the applicants requested 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 and no comments were raised on the substance of the health claims.

**Vote taken:** unanimous in favour.

**B.3** Exchange of views and possible opinion of the Committee on a draft Commission Regulation correcting the Lithuanian language version 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 Commission Regulation which will correct the Lithuanian version of Regulation (EU) No 432/2012. The Commission explained that the other linguistic versions are not affected. The Lithuanian Authorities have been consulted for all the suggested linguistic changes.

**Vote taken:** unanimous in favour.


The draft Commission Regulation aims at updating the positive lists of vitamin and mineral substances included in the Annexes of the above-mentioned acts, following the favourable assessment of two new mineral substances by the European Food Safety Authority (EFSA).

Concretely, this draft Regulation aims at adding chromium enriched yeast, as a source of chromium, to Annex II of Directive 2002/46/EC on food supplements and chromium (III) lactate tri-hydrate, as a source of chromium, to Annex II of Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods.

Concerns were raised by one Member State regarding the inclusion of these two chromium substances in the relevant Annexes without making reference to an upper limit in the draft Regulation with regard to chromium intake. Products on the market may contain high amounts of chromium and result in intakes of that nutrient that would be of concern. The Commission noted that the authorisation of sources of vitamins and minerals is not an appropriate means of limiting the use of these nutrients in the absence of harmonised maximum amounts for them. It was recalled that in the absence of EU harmonised maximum amounts, Member States may apply national ones taking into account the criteria set in the relevant EU legislation.

Another Member State expressed concerns regarding the intake of lactose resulting from the use at certain levels of chromium (III) lactate tri-hydrate and referred to the requirement, under the Regulation on food information to
consumers, of mentioning the lactose content on the labelling of the product. The Commission explained that, according to the EFSA assessment, the intake levels of lactose from chromium (III) lactate tri-hydrate are not of safety concern as these would be significantly below tolerable levels of individuals with lactose maldigestion.

Finally, one Member State raised concerns in relation to the inclusion of chromium enriched yeast in the positive list as it was presented in the draft. More specifically it raised concerns that the reference to the substance was not specific enough in the draft Commission Regulation despite the fact that EFSA had stated in its conclusions that the favourable assessment only applies to the specific chromium yeast, obtained by culture of *Saccharomyces cerevisiae* in the presence of chromium (III) chloride. The Commission amended the draft Commission Regulation accordingly.

**Vote taken:** favourable opinion by qualified majority (323 in favour, 29 abstentions).

B.5 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision authorising the placing on the market of rooster comb extract as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council.

The Commission presented the draft Implementing Decision to authorise the use of rooster comb extract as a novel food and introduced few editorial corrections to the text. The Commission noted that the food "fromage frais" is to be included in italics and without translating in all languages versions.

**Vote taken:** favourable opinion by qualified majority (340 in favour, 12 abstentions).

C.1 Exchange of views of the Committee on a draft Commission 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 Commission Regulation (EU) No 432/2012.

As provided for in Article 18(4) of Regulation (EC) No 1924/2006 Member States were consulted on a health claim submitted pursuant to Article 13(5) of that Regulation, which received a favourable assessment by the European Food Safety Authority (EFSA).

The Commission presented the draft Regulation and one Member States raised concerns on the formulation of the conditions of use and in particular requested Sugar Beet Fibre to be clearly stated in the conditions of use by replacing the word 'that fibre'.

Commission clarified that the way the conditions of use have been formulated it is consistent with the conditions of use for similar claims listed in the Annex of Regulation (EU) 432/2012 and that a food, in order to be eligible for the claim, should be high in Sugar Beet Fibre and not any other fibre.
Following the exchange of views, there was consensus on the draft Commission Regulation.

C.2 Exchange of views 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.

The draft Commission Regulation was submitted to the Standing Committee in accordance with Article 18(5) of Regulation (EC) No 1924/2006. This draft Commission Regulation refuses to authorise the use of five health claims provided for in Article 13(5) of that Regulation based on newly developed scientific evidence and/or which include a request for the protection of proprietary data. More specifically, the applications subject to this draft measure relate to the effects of:

- Yestimun® and defence against pathogens in the upper respiratory tract;
- Transitech® and improvement of bowel function which is maintained after cessation of consumption of the food;
- Bimuno® GOS and reducing gastro-intestinal discomfort;
- Lactobacillus rhamnosus GG and maintenance of normal defecation;
- VeriSol®P and a change in skin elasticity leading to an improvement in skin function.

The Commission presented the draft and the health claims therein.

On the health claim on Lactobacillus rhamnosus GG, one Member State expressed concerns about the drafting of recital 12 and in particular the reasons on which this health claim should be rejected.

The comments expressed during that discussion will be taken into account by the Commission in finalising its decision, and the issue is referred for further discussions at experts' level.


This item has been withdrawn from the agenda.