Chairman: Mr Basil Mathioudakis

All Member States were present except Bulgaria, Portugal and Poland, which were represented.


As provided for in Article 18(4) of Regulation (EC) No 1924/2006 Member States were consulted on a health claim provided for in Article 13(5) of that Regulation, which received a favourable assessment by the European Food Safety Authority (EFSA). The health claim is related to monacolin K in SYLVAN BIO red yeast rice and maintenance of blood LDL-cholesterol concentrations. The applicant proposed an intake of SYLVAN BIO red yeast rice equivalent to 4.08 mg/day of monacolin K.

The Commission presented the working document and informed the delegations that EFSA concluded that the evidence provided by the applicant does not establish that monacolin K in SYLVAN BIO RYR is different from monacolin K in other red yeast rice preparations with respect to its effect on blood LDL-cholesterol concentrations. A claim on monacolin K from red yeast rice and maintenance of normal blood LDL-cholesterol concentrations has already been assessed with a favourable outcome in 2011. In addition, the Commission pointed out that in relation to the restrictions of use, EFSA in its opinion made reference to the Summary of Product Characteristics of lovastatin-containing medicinal products available on the EU market and to EFSA CONTAM Panel’s opinion on citrinin (a nephrotoxic mycotoxin) which can be produced by some strains of Monascus purpureus.

All the delegations who intervened expressed their concerns about side effects of lovastatin containing products and about the presence of citrinin in red yeast rice preparations and asked the Commission to refer back to EFSA for a safety evaluation.
Regarding the side effects of consumption of monacolin K, the Commission recognised the concerns expressed by the Member States on the safety aspects of the product and the need to explore, in collaboration with Member States, the best way to address them.

Concerning the presence of citrinin in red yeast rice preparations, Member States were informed that, following the opinion of EFSA CONTAM Panel on citrinin in red yeast rice preparations, internal discussions have been on-going within the Commission on the necessity to establish maximum levels within the contaminants legislation for citrinin in red yeast rice preparations.

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

A.2 Exchange of views of the Committee on a Working document by the Commission services for consultation of Member States on three health claims related to Yestimun® - (Question No EFSA-Q-2012-00761), plant stanol esters - (Question No EFSA-Q-2012-00915), Eicosapentaenoic acid (EPA) - (Question No EFSA-Q-2012-00573), pursuant to Regulation (EC) No 1924/2006 (Art.13(5) 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 8 April 2013. More specifically, the applications subject to this working document related to the effects of:

•Plant stanol esters and reduction of blood LDL-cholesterol concentrations as part of a diet low in saturated fat

•EPA and reduction of AA/EPA ratio in blood in children with attention deficit hyperactivity disorder (ADHD)

In addition, Member States were also consulted on a health claim provided for in Article 13(5) of Regulation (EC) No 1924/2006, for which EFSA published its opinion on 8 April 2013. More specifically, the application subject to this working document related to the effects of Yestimun® and defence against pathogens in the upper respiratory tract.

The Commission presented the working document and the health claims therein and no comments were raised on the substance of the health claims.

These health claims will be referred for further discussion at experts’ level and will be presented for the opinion of the Committee in a future meeting.


The draft Directive would amend Directive 2006/141/EC with respect to protein requirements for infant formulae and follow-on formulae. First, it would authorise the placing on the market of infant formulae and follow-on formulae
manufactured from goats' milk proteins on the basis of an opinion by the
European Food Safety Authority (EFSA) of 28 February 2012 (request No. EFSA-Q-2011-00132). Second, it would authorise the placing on the market of follow-on formulae manufactured from protein hydrolysates with a protein content of 1.9g/100 kcal (a lower content than what is today foreseen) taking into account EFSA’s opinion of 5 October 2005 (request No. EFSA-Q-2005-040).

The Commission presented the draft and recalled that the issue was already discussed on the basis of a Working Document, during a previous meeting of the Committee, with no opposition from Member States.

Following questions from one Member State, the Commission provided some background on the difference in protein quality requirements foreseen in Annex V and VI of Directive 2006/141/EC. The Commission underlined how the differences between Annex V and VI will be brought to the attention of EFSA in the context of the opinions on milk-based drinks and similar products intended for infants and young children on which the Authority is currently working (requests No. EFSA-Q-2013-00263 and EFSA-Q-2013-00264).

Another Member State asked the Commission whether it intends to ask EFSA to specifically consider goat milk in the work that the Agency is currently carrying out on allergens. The Commission noted that EFSA was reviewing the issue of allergens.

A third Member State asked whether it would be possible to foresee a longer period to transpose the Directive into national legal orders. This was however not accepted due to the limited and technical nature of the amendments that the draft Directive will introduce.

Two Member States asked whether it would be necessary to introduce in the Directive a requirement for operators to indicate the animal source of protein of infant formulae and follow-on formulae. The Commission considered this not to be necessary, since it was expected that operators that will manufacture products from goats' milk protein will have an interest in communicating this information voluntarily to consumers. The issue will however be further monitored and considered in the context of discussions for the forthcoming delegated act on infant formulae and follow-on formulae.

Following comments from one Member State, an editorial change was made to a recital of the draft Directive to improve the description of the existing provisions of Directive 2006/141/EC with respect to formulae manufactured from protein hydrolysates.

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 is a merged version of two draft Commission Regulations already submitted to previous meetings of the Standing Committee for discussion. It aims at adopting a decision, in accordance with Article 18(5) of Regulation (EC) No 1924/2006, refusing to authorise the use of eight 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 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, including the EFSA opinions, the comments submitted pursuant to Article 16(6) of the Regulation (EC) No 1924/2006 and EFSA’s responses to those comments. An exchange of views took place.

Two delegations questioned EFSA's conclusion on the health claim on spermidine and prolongation of the growing phase (anagen) of hair cycle as a health claim referring to the treatment of a disease and noted that telogen effluvium is caused by multifactorial triggers which are not always related to a disease. Furthermore, they noticed that treating some of the symptoms of a disease does not always have the meaning of treating the disease itself.

**Vote taken:** unanimous in favour.

### C.1 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 is a merged version of two draft Commission Regulations already submitted to previous meetings of 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 seventeen health claims provided for in Article 13(5) of that Regulation.

More specifically, the applications subject to this draft measure relate to the effects of:

- Glucosamine and maintenance of joints
- Glucosamine and maintenance of normal joint cartilage
- Wheat polar lipid extract and protection of the skin against dehydration
- *Saccharomyces cerevisiae* var. *boulardii* CNCM I-3799 and reducing gastrointestinal discomfort
- A combination of thiamin, riboflavin, niacin, pantothenic acid, pyridoxine, D-biotin and pumpkin seed oil (*Cucurbita pepo* L.) and maintenance of normal hair
Rhodiola rosea L. extract and reduction of mental fatigue

A combination of flaxseed oil and vitamin E and maintenance of the skin permeability barrier function

Opti-EFAX™ and maintenance of normal blood LDL-cholesterol concentrations

Opti-EFAX™ and maintenance of normal blood HDL-cholesterol concentrations

KF2BL20, which is a combination of keratin, copper, zinc, niacin, pantothenic acid, pyridoxine and D-biotin, and maintenance of normal hair

Hyaluronic acid and protection of the skin against dehydration

Opti-EFAX™ and maintenance of normal blood concentrations of triglycerides

“Transitech®” and improves transit and durably regulates it

“Femilub®” and maintenance of vaginal moisture

A combination of lycopene, vitamin E, lutein and selenium and protection of the skin from UV-induced damage

Prolibra® and helps to reduce body fat while preserving lean muscle

EffEXT™ and “helps to support joint function by maintaining low levels of plasma C-reactive protein”

The Commission presented the draft and the health claims therein and no comments were raised on the substance of the health claims. The draft Regulation will be referred for further discussion and possible opinion of the Committee in the next meeting.

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 thirteen health claims provided for in Article 13(5) of that Regulation. More specifically, the applications subject to this draft measure relate to the effects of:

- Zinc and prevention of bad breath
- L-tyrosine and contribution to normal synthesis of dopamine
- Iron and maintenance of normal hair growth
• Citrulline-malate and faster recovery from muscle fatigue after exercise

• EffEXT™ and maintenance of normal joint mobility

• Krill oil and maintenance of joint comfort

• Vitis vinifera L. seeds extract and normal venous blood flow

• Vitis vinifera L. seeds extract and “Helps to decrease swollen legs”

• Cynatine® and maintenance of normal joint mobility

• OXY 280 and reduction of body weight

• Vitis vinifera L. seeds extract and “Helps to drain the body in case of water accumulation”

• A combination of Paullinia cupana Kunth (guarana) and Camellia sinensis (L.) Kuntze (green tea) extracts and reduction of body weight

• A combination of lycopene, vitamin E, lutein and selenium and “Helps to prepare and activate tanning”

The Commission presented the draft and the health claims therein and no comments were raised on the substance of the health claims.

The draft Commission Regulation will be referred for further discussion at experts’ level and will be presented for the opinion of the Committee in a future meeting.

C.3 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 six health claims provided for in Article 13(5) of that Regulation.

More specifically, the applications subject to this draft measure relate to the effects of:

• A combination of B. longum LA 101, L. helveticus LA 102, L. lactis LA 103 and S. thermophilus LA 104 and intestinal discomfort

• A combination of B. longum LA 101, L. helveticus LA 102, L. lactis LA 103 and S. thermophilus LA 104 and stool frequency

• EFAXTM and reduction of menstrual discomfort
• Slendesta® Potato Extract and reduction of body weight

• Monurelle® and reduction of bacterial colonisation of the urinary tract

• Vichy Catalan carbonated natural mineral water and reduction of post-prandial lipaemic response

The Commission presented the draft and the health claims therein.

One Member State reminded the Committee of the comments which were received by the applicant on the health claim on Slendesta® Potato Extract and questioned the classification of the health claim on Monurelle® as a health claim under Article 13.5 and not as a risk reduction health claim (Article 14.1(a)). The Commission informed the Committee that the comments received on the health claim on Slendesta® Potato Extract were of scientific nature and were thus forwarded to EFSA for scientific advice.

The Commission also reminded Member States, in the context of the classification of health claims, the important role of their competent authorities, when receiving an application for the authorisation of a health claim, in carrying out the validity check.

The draft Commission Regulation will be referred for further discussion at experts’ level and will be presented for the opinion of the Committee in a future meeting.

M.1 Information from Sweden on the results from the Swedish National Food Agency’s study on mineral and heavy metal content in foods for infants and young children.

Sweden informed the Committee on the results of a study conducted by the Swedish National Food Agency in 2011-12 on the content of arsenic, cadmium and lead, iron copper and manganese in foods intended for infants and young children, including foods for special medical purposes.

The Swedish delegation explained that the study reveals that many of the food products examined contain arsenic, lead and cadmium and high levels of manganese that, in the view of the Swedish Agency, potentially pose health problems in infants and young children.

On the basis of these conclusions, the Swedish delegation presented the follow-up recommendations of their National Food Agency on the matter. These include, among others, recommendations for EFSA (e.g. to revise the recommended intakes and upper safe levels of iron, copper and manganese) and recommendations for risk managers. With respect to the latter, it is recommended to continue work at EU level on heavy metals in food for infants and young children in the context of the implementation of Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foods. It is also recommended to address a series of issues with respect to manganese and, in general, to the presence of minerals in foods for infants and young children in the context of the forthcoming discussions on delegated acts to be adopted for such products.
The Committee welcomed the presentation and took good note of the study presented by the Swedish delegation. Three delegations commented that the results with respect to contaminants are particularly worrying and underlined how they are considering action either on the basis of the Swedish study or of similar studies being carried out in their territory.

The Commission recalled that work on heavy metals in food for infants and young children is indeed on-going. It then underlined how recommended intakes of minerals will be considered by EFSA in the context of the opinion that is currently being prepared on dietary requirements of infants and young children (in the framework of advice to be provided on milk based-drinks and similar products intended for infants and young children). Similarly, recommended intakes of minerals for infants and young children will also be considered, where possible, during work on the opinions on dietary reference values. The Commission confirmed that the risk management recommendations made in the study will be further considered during the forthcoming discussions on delegated acts to be adopted for foods intended for infants and young children.

M.2 Request from Czech Republic of discussion on the labelling of COCAINE double energy drink.

The Czech Republic informed the Committee that they received a notification of a food which is intended to be marketed in the Czech Republic under the name "COCAINE double energy drink" and sought the opinion of the Commission and other Member States on whether such a product can be legally placed on the market.

During the exchange of views, one delegation questioned the safety of this product in relation to its high content of caffeine compared to the other energy drinks that are on the market and indicated that a safety assessment of the product should be carried out before its marketing. The majority of the Member States that intervened, considered that the indication "COCAINE double energy drink", either used as a brand name, trademark or as part of the name of the product, should be prohibited or restricted. In particular it was noted that the product name could be misleading for the consumer as cocaine is not an ingredient of this product. One Member State considered that this indication displayed on food labelling is not misleading for the consumer.

The Commission underlined that, in accordance with the general requirements of EU food law, foods which are not safe cannot be placed on the market. Food business operators are primarily responsible for ensuring compliance with the relevant food safety requirements. It was stressed that as a general rule food labelling must not mislead the consumer as to the nature and identity of the food. Moreover, the name of the food must be clear enough to let the consumer know its true nature and distinguish it from any other product. The Commission reiterated the position endorsed by the Committee during the meeting of 30 April 2012 on the issue of marketing of foods containing cannabis extract: namely, that the labelling of foods promoting their alleged drug effects or making the notion "drug" seem to be part of everyday life should be considered as illicit and
misleading. The competent authorities of the Member States have the responsibility to assess, on a case by case basis, if a food label is likely to mislead the consumer or to encourage or condone consumption of narcotics and ultimately hurt public order or morality.

M.3 Request from United Kingdom of discussion on the assessment of the suitability of the use of a probiotic strain in infant formula and follow-on formula.

The UK informed the Committee of the way it handled a notification received from a manufacturer of an infant formula containing a specific voluntary ingredient (the micro-organism Lactobacillus fermentum). The UK delegation explained that their Scientific Advisory Committee on Nutrition’s Subgroup on Maternal and Child Nutrition assessed the suitability of the ingredient in infant formula and follow-on formula for particular nutritional uses by infants in accordance with articles 5 and 6 of Directive 2006/141/EC. Following the conclusion that the evidence presented was not sufficient to demonstrate such suitability, the UK authorities concluded that the product in question would not comply with Directive 2006/141/EC and agreed with the manufacturer a procedure to remove the ingredient from products on the UK market.

The UK delegation first underlined that it was aware of the product having been notified in other Member States and it asked other delegations to confirm that this was indeed the case. Several Member States confirmed that either this product or other products with similar ingredients were notified in their territory. Different reactions were reported with respect to the right of these products to be placed on the market.

The UK delegation then asked the Commission whether the procedure they followed was in line with EU legislation. The Commission explained that, in line with EU law and the rules of the Treaty, a Member State can restrict the marketing of an infant formula or a follow-on formula if they have justified grounds to do so. In particular, in the case of infant formulae and follow-on formulae containing ingredients not specified in Directive 2006/141/EC, Articles 4 to 6 of the Directive are relevant. According to these Articles, when a food business operator places a product with a new ingredient on the market, 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 and it is their right to consider that the ingredient does not meet the requirements of Articles 4 to 6 and to refuse the placing on the market of products with such ingredient. In this context, the Commission recalled that the concept of suitability includes elements of safety and expected benefits and that in order to assess the latter, evaluations carried out by EFSA on specific substances in the context of the implementation of Regulation (EC) No 1924/2006 on nutrition and health claims can also provide a useful tool for national competent authorities.

The UK delegation finally underlined that they would support the establishment of a centralised prior authorisation procedure at EU level for addition of new non-essential ingredients to infant formulae and follow-on formulae, based on the advice of the European Food Safety Authority with regard to the safety and suitability of the ingredient. The Commission concluded that it will be possible to
further discuss this issue during discussions on the forthcoming delegated act on infant formulae and follow-on formulae.