1. Exchange of views of the Committee on Sytrinol complaint by the company Innocoetics - Non compliance with Commission Regulation (EC) No 258/97 by the Dutch authorities.

Sytrinol is an alcoholic extract from Mandarine peels that provides in particular the flavones Nobilitin and Tangeritin.

There are 2 questions on which Member States will investigate and provide information to the Commission by mid September.

A) Information whether such an extract from Mandarin peels was on the market in any Member State and if so to what degree.

B) Technical judgement to what extent the alcoholic extracts from Mandarine peels used in alcoholic beverages are significant for the use of this extract (Sytrinol) in food supplements.

For both questions Member States need to look for more information about the product Sytrinol and also about the extracts used in alcoholic beverages.


The draft Regulation aims at updating the lists of vitamins and minerals included in the Annexes of the above acts, following the assessment of new mineral substances by the European Food Safety Authority (EFSA).
Concern was raised by a Member State regarding the inclusion of Chromium picolinate in the relevant Annexes as there is currently no maximum amount set up at EU level for chromium. 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.

Another Member State expressed concerns regarding the intake of EDTA resulting from the use at certain levels of ferric sodium EDTA in foods intended for infants and young children and in foods for special medical purposes when these latter are used as the sole source of nourishment.

The Commission explained that it is the responsibility of food business operators to ensure that foods placed on the market are safe for the intended use taking into account all available scientific data. It was noted in particular that as regards the use of ferric sodium EDTA, EFSA concludes on its safe use as long as it does not lead to an exposure to EDTA above 1.9 mg EDTA/kg bw/day.

Vote: Favourable opinion by qualified majority (303 in favour; 29 abstained, 13 absent).


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 one health claim and rejecting two health claims provided for in Article 14(1)(a) of that Regulation.

The Commission presented the draft and the health claims therein, including the relevant EFSA opinions and the EFSA response to the comments submitted by the applicant and/or members of the public pursuant to Article 16(6) of Regulation (EC) No 1924/2006.

The health claim to be authorised related to the effects of oat beta glucan on the reduction of blood cholesterol, which is a risk factor in the development of coronary heart disease. One delegation expressed the view that the foods bearing the health claim should provide the totality of the daily intake necessary to achieve the beneficial effect, i.e.: 3g of oat beta glucan per quantified portion. This would ensure that the consumer obtains the necessary quantity of the substance subject of the claim and at the same time avoid excess consumption of foods which could lead to excess intake of energy at a time when overweight and obesity were becoming a problem.
The Commission explained that the conditions of use accompanying the claim would ensure that the consumer is fully informed about the amount of oat beta glucans to be consumed daily. In addition, conditions of use set can be met by a range of foods which would allow the intake of the quantity of the substance necessary for the beneficial effect to be ingested through a normal diversified diet.

In the light of a favourably assessed Article 13(1) claim on beta glucans and maintenance of normal blood cholesterol with a daily intake of 3g of oat beta glucans, one delegation considered that the target population of claims should be defined to allow consumers to distinguish between Article 13(1)(a) claims, valid "for normocholesterolemics" and Article 14(1)(a) claims, valid "for hypercholesterolemics ".

The Commission noted the issue and considered that it should be dealt with in a more comprehensive way, once the discussions on Article 13(1) are more advanced. Further, pending decisions on Article 13(1) claims, the Commission explained that coherence should be ensured with Article 14(1)(a) similar claims which have been authorised previously without such specification of the target population.

The health claims to be rejected related, for one application, to the effects of soy protein on the reduction of blood cholesterol and for the other application, to the effects of Actimel® fermented milk containing a probiotic bacterial strain on the reduction of Clostridium difficile toxins in the gut (of susceptible ageing people), which is associated with the incidence of acute diarrhoea. One delegation expressed concerns regarding the scientific assessment of the latter.

The exchange of views and an editorial change on the draft measure was agreed during the meeting.

Vote: Favourable opinion by qualified majority (275 in favour, 29 against, 41 abstentions).


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 rejecting two health claims provided for in Article 14(1)(a) of that Regulation.

The Commission presented the draft and the health claims therein, including the relevant EFSA opinions and the responses to the comments submitted by the applicant and/or members of the public pursuant to Article 16(6) of Regulation (EC) No 1924/2006.
Regarding one application related to the effects of water on the reduction of dehydration and concomitant decrease of performance, the Commission recalled that Member States agreed in a previous meeting, that Article 14(1)(a) claims shall refer to the reduction of an identified risk factor in the development of a human disease, in accordance with the definition of these health claims provided for in Article 2(6) of Regulation (EC) No 1924/2006. Accordingly, it was considered that in the absence of substantiation on the reduction of a valid risk factor, the claim does not comply with the requirements of Regulation (EC) No 1924/2006.

The other application related to the effects of calcium containing fruit juices in replacement of fruit juice without added calcium and the reduction of tooth demineralisation which is a risk factor in the development of tooth erosion.

*Vote: Favourable opinion unanimously.*


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 two health claims foreseen in Article 13(5) of that Regulation.

The Commission presented the draft and the health claims therein, including the relevant EFSA opinions and the responses to the comments submitted by the applicant and/or members of the public pursuant to Article 16(6) of Regulation (EC) No 1924/2006.

One application related to the effects of *Lactobacillus plantarum* TENSIA™ in the semi-hard Edam-type "heart cheese" of Harmony™ and maintenance of normal blood pressure and one application related to the effects of *Lactobacillus casei* strain Shirota in a fermented milk product on maintenance of upper respiratory tract defences by helping to support immune functions.

The exchange of views and an editorial change on the draft measure was agreed during the meeting.

*Vote: Favourable opinion by qualified majority (329 in favour, 16 abstained).*

6. Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision authorising the placing on the market of fermented black bean extract as a novel food ingredient. (Art. 7 of Regulation (EC) N° 258/97) (Opinion of the Committee via the examination procedure) (Doc. SANCO/11634/2011)

Some editorial changes but also amendment of the labelling to include reference to Soya in the labelling were forwarded before the meeting. (The designation will be 'fermented black bean (Soy) extract' or 'fermented Soya extract'.)
Vote: Favourable opinion by qualified majority (318 votes in favour, 27 votes abstention) (Ireland was represented by Malta; Bulgaria was represented by Belgium, Slovakia was represented by Slovenia).

7. Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision authorising the placing on the market of yeast beta-glucans as a novel food ingredient. (Art. 7 of Regulation (EC) N° 258/97) (Opinion of the Committee via the examination procedure) (Doc. SANCO/11633/2011)

It was agreed that Annex II of the draft Commission Implementing Decision (uses and use levels of yeast beta glucan) will require major amendments to enable effective implementation and clarity in forthcoming notifications by other applicants. Therefore an amended version of this draft will be presented at the next meeting for an opinion. Member States may send their contributions by the end of the month to the Commission.

Vote: postponed.

8. Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision authorising the placing on the market of Soya Phosphatidylserine Phospholipids as a novel food ingredient. (Art. 7 of Regulation (EC) N° 258/97) (Opinion of the Committee via the examination procedure) (Doc. SANCO/11631/2011)

Some editorial changes for clarification were agreed. In particular, 'Soya Phosphatidylserine Phospholipids' were replaced by 'Phosphatidylserine from Soya Phospholipids'.

Vote: Favourable opinion by qualified majority (316 votes in favour; 29 votes abstention). (Ireland was represented by Malta; Bulgaria was represented by Belgium).

9. Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision authorising the placing on the market of phosphated maize starch as a novel food ingredient. (Art. 7 of Regulation (EC) N° 258/97) (Opinion of the Committee via the examination procedure) (Doc. SANCO/11632/2011)

Some editorial changes were agreed. For clarification 'baked products' are to be called 'baked bakery products'.

Vote: Favourable opinion by qualified majority (316 votes in favour; 29 votes abstention). (Ireland was represented by Malta; Bulgaria was represented by Belgium).
10. Exchange of views of the Committee 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 and to children's development and
health (Art. 14(1) of Regulation (EC) No 1924/2006). (Regulatory procedure with
scrutiny of the European Parliament and of the Council)
(Doc. SANCO/11587/2011)

The draft Commission Regulation was submitted to the Standing Committee in
accordance with Article 17(1) of Regulation (EC) No 1924/2006. It would authorise two
health claims provided for respectively in Article 14(1)(a) and in Article 14(1)(b), and
would reject two health claims provided for in Article 14(1)(a) of that Regulation.

More particularly, one application related to the effects of the replacement of saturated
fatty acids by mono- and/or polyunsaturated fatty acids on reduction of blood
cholesterol, which is a risk factor in the development of coronary heart disease. One
application related to the effects of alpha-linolenic acid (ALA) on the brain and nerve
tissue development of infants and young children. Two applications related to the effects
of ProteQuine®, a mixture of free amino acids, oligopeptides and nucleotides on
increase of suppressed concentrations of secretory immunoglobulin A and reduction of
the risk of common cold and of ProteQuine® with bovine lactoferrin on increase of
suppressed concentrations of secretory immunoglobulin A and reduction of the risk of
common cold with sore throat.

The Commission presented the draft and the health claims therein, and a number of
issues were raised, especially with regard to the possibility to authorise health claims
referring to the replacement of one food or its constituents by another and the setting of
appropriate conditions of use. As these issues were of a technical nature, the draft
Regulation will be referred for further discussions at experts' level and put to the vote of
the Committee in a future meeting.

11. 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 (Art. 13(5) of
Regulation (EC) No 1924/2006). (Regulatory procedure with scrutiny of the

The draft Commission Regulation was submitted to the Standing Committee in
accordance with Article 18(5) of Regulation (EC) No 1924/2006. It would refuse to
authorise the use of one health claim foreseen in Article 13(5) of that Regulation.

More specifically, the application subject to this draft measure relates to the effects of
*Lactobacillus rhamnosus* GG (LGG) on maintenance of defence against intestinal
pathogens.

The Commission presented the draft and the health claims therein. The draft was
referred to for further discussions at experts' level and will be put to the vote of the
Committee in a future meeting.

During the consultation of the Member States which took place at the meeting of the Standing Committee on 21 February 2011 (see relevant Summary Record), as provided for in Article 18(4) of Regulation (EC) No 1924/2006, several delegations expressed concerns regarding the relevance of the particular health claim to consumers, insofar as the EFSA opinion had noted that evidence supported the proposed claim in frequent consumption of juice drinks (4 daily exposures) and sugar-containing acidic drinks (7 daily exposures).

The Commission explained that following careful consideration of the application, additional advice has been requested to EFSA, namely asking whether the beneficial effect is shown or expected to be shown for less frequent consumers of sugar-containing acidic drinks, with substitution, in particular of at least one serving of juice drinks and sugar-containing drinks.

EFSA representative presented the supplementary EFSA opinion (EFSA-Q-2011-00781) where it was concluded that "for people who are also frequent consumers of sugars and/or acids from other beverages and foods that can contribute to tooth demineralisation, a beneficial effect on maintaining tooth mineralisation may be expected by substitution of one or more servings of conventional juice drinks or sugar-containing non-alcoholic beverages with an equivalent number of servings of 'toothkind' juice drink".

The Commission noted that the beneficial effect is expected with lower substitution rates than those used in the studies substantiating the claim and asked for Member States' reactions.

Two delegations expressed concerns regarding potential wording of the claim in products bearing the claim that may refer negatively to fruit juices. One delegation stressed that the authorisation of claims, according to the Regulation, shall have a generic effect and considered that this would be ensured if the trademark 'toothkind' is not included in the wording of the claim.

The Commission noted the concerns expressed by the delegations which will be taken into account by the Commission in finalising its decision. Further, it indicated that any other comments on the same issue could be made during the next experts' working group.

**Miscellaneous**