A.01 Exchange of views of the Committee on a Working document prepared by the Commission services for consultation of Member States on four health claims related to vitamin C and increasing non-haem iron absorption (Question No-EFSA-Q-2008-176), iron and contribution to normal formation of haemoglobin and red blood cells (Question No-EFSA-Q-2008-147), iodine and contribution to normal thyroid function (Question No-EFSA-Q-2008-144) and iodine and contribution to normal cognitive development (Question No-EFSA-Q-2008-145) pursuant to Regulation (EC) No 1924/2006

As provided for in Article 17(1) of Regulation (EC) No 1924/2006, Member States were consulted on four health claims provided for in Article 14(1)(b) of that Regulation which have received a favourable assessment by the European Food Safety Authority (EFSA). EFSA's scientific opinions were published on 10 January 2014.

More specifically, the applications subject to this working document relate to the effects of:

- Vitamin C and increasing non-haem iron absorption;
- Iron and contribution to normal formation of haemoglobin and red blood cells;
- Iodine and contribution to normal thyroid function;
- Iodine and contribution to normal cognitive development.
One Member State considered that an authorisation of these health claims may be premature considering that discussions are on-going in the context of Regulation (EU) No 609/2013 on foods for specific groups.

The Commission confirmed that these claims would be considered in parallel with the work on the implementation of Regulation (EU) 609/2013 and noted that, while these claims remain 'on hold' pending a decision, they may be used on existing products placed on the market.

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.

A.02 Exchange of views of the Committee on a Working document prepared by the Commission services for consultation of Member States on five health claims related to non-digestible carbohydrates and a reduction of post-prandial glycaemic responses (Question No EFSA-Q-2013-00615), Padina pavonica-extract in Dictyolone® and an increase in bone mineral density (Question No EFSA-Q-2013-00249), "Orzotto" and protection of blood lipids from oxidative damage (Question No EFSA-Q-2013-00578), a combination of diosmin, troxerutin and hesperidin and maintenance of normal venous-capillary permeability (Question No EFSA-Q-2013-00353) and a combination of diosmin, troxerutin and hesperidin and maintenance of normal venous tone (Question No EFSA-Q-2013-00354) pursuant to Regulation (EC) No 1924/2006

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 one favourably assessed Article 13(5) health claim for which EFSA published its opinion on 10 January 2014. More specifically, the application subject to this working document related to the effects of non-digestible carbohydrates and a reduction of post-prandial glycaemic responses.

The Commission pointed out that, in its opinion, EFSA noted that non-digestible carbohydrates have a neutral taste and cannot substitute for the sweet taste of sugars.

One Member State highlighted the importance of defining the term "non-digestible carbohydrates" prior to authorising the health claim.

Another Member State pointed out that there is an already authorised Article 13(1) health claim on sugar replacers and blood glucose rise and suggested that the conditions of use are set taking into consideration those of the authorised Article 13(1) claim.

In addition, the Member States were also consulted on four health claims provided for in Article 13(5) of Regulation (EC) No 1924/2006, for which EFSA published its opinions on 10 and 13 January 2014. More specifically, the applications subject to this working document related to the effects of:

- Padina pavonica-extract in Dictyolone® and an increase in bone mineral density
  – unfavourable assessment
• "Orzotto" and protection of blood lipids from oxidative damage - unfavourable assessment
• A combination of diosmin, troxerutin and hesperidin and maintenance of normal venous-capillary permeability - unfavourable assessment
• A combination of diosmin, troxerutin and hesperidin and maintenance of normal venous tone - unfavourable assessment

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

A.03 Exchange of views of the Committee on a Slovak notification of a draft Decree on bakery products, confectionery products and pasta (2013/483/SK)

This item has been withdrawn from the agenda.

A.04 Request from the United Kingdom for a discussion on Article 1.2(b) of Commission Directive 1999/21/EC on dietary foods for special medical purposes

On the request of the UK the Committee discussed whether a product containing a combination of nutrients such as vitamins, minerals and omega-3 fatty acids and marketed "For the dietary management of early Alzheimer's disease" would fall within the scope of the definition of Food for Special Medical Purposes (FSMP), according to Article 1(2)(b) of Commission Directive 1999/21/EC on dietary foods for special medical purposes.

The UK delegation explained that their authorities are currently in talks with an operator who manufactures a product with this composition. After having informed the operator of their initial doubts that the product would comply with the definition of FSMP, the UK authorities were asked by the operator to reconsider their decision since the product is also marketed as an FSMP in other Member States. The UK delegation therefore asked for the views of other Member States and in particular whether the principle of mutual recognition applies in this situation.

Discussions within the Committee confirmed that the product is on the market of different Member States as an FSMP. Of the delegations that intervened, one explained that the product was accepted because of the principle of mutual recognition. Another one explained that the product was accepted following an assessment of the data submitted by the operator. The operator was however asked to market the product "for the dietary management of cognitive loss among the elderly population" rather than "for the dietary management of early Alzheimer's disease". Another delegation explained that the matter is currently being assessed by their national scientific authority in order to understand whether early Alzheimer's disease patients have special dietary needs.

Several delegations intervened in support of the position of the UK authorities that the product would not comply with the definition of FSMP and a request was made that the broader issue of classification of products as FSMPs is tackled by the Commission in a guidance document.
The Commission noted that increasing numbers of products appear to be notified as FSMPs in Member States. This may be due to the implementation of the Regulation on nutrition and health claims and to the forthcoming abolition of the concept of dietetic foods. In that context, the marketing of a product as a FSMP, instead of as a food bearing a claim, could enable it to be placed on the market with a statement that refers to the dietary management of a disease, disorder or medical condition, following only notification of the product to the competent authorities, rather than following the procedure for authorisation of a health claim. While the final decision on the classification of products lies with the national competent authorities, discussions in the Committee can provide guidance on the matter. Further it was recalled that as of 20 July 2016, the Commission will also have the right, pursuant to Article 3 of Regulation (EU) No 609/2013 on food for specific groups, to adopt implementing measures to decide whether a given food falls within the scope of the Regulation and, for example, whether a given food would be a FSMP. The Commission also took note of the request of the delegations to provide advice to national authorities in the context of a guidance document.

The Commission clarified that the principle of mutual recognition does not apply in areas where the legislation is harmonised and is therefore not relevant in an area where Directive 1999/21/EC provides harmonised rules, including a definition, that are applicable to FSMPs throughout the EU. The matter brought forward by the UK delegation is related to the application of the legislation by the national competent authorities, who have the right and obligation to ensure that products on their market comply with the relevant EU legislation. Decisions of national authorities can be challenged in courts, and the ultimate responsibility for the interpretation of EU law lies with the Court of Justice of the EU.

The Commission recalled the definition of FSMPs given in Article 1(2)(b) of Directive 1999/21/EC and drew the attention of Member States on the consequences that a broad interpretation of this definition could entail. In this context, it called on Member States to take into account all the elements of the definition, including the one whereby FSMPs are intended for "(...) medically-determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet (...)"). The Commission underlined that food supplements are regulated as foods and modification of the normal diet can include use of food supplements. It suggested that Member States pay particular attention to whether products notified as FSMPs would not in fact be food supplements.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Regulations (EC) No 983/2009 and (EU) No 384/2010 as regards the conditions of use of certain health claims related to the lowering effect of plant sterols and plant stanols on blood LDL-cholesterol

The draft Commission Regulation aims at amending Regulations (EC) No 983/2009 and (EU) No 384/2010 as regards the conditions of use of certain health claims related to the lowering effect of the plant sterol and plan stanols on blood LDL-cholesterol on the basis of two applications submitted under Article 14(1)(a) and Article 19 of Regulation (EC) no 1924/2006.

The conditions of use of the authorised health claims on plant sterols, plant stanol esters and plant sterols/plant stanol esters, as laid down in Regulations (EC) No
983/2009 and (EU) No 384/2010, provide that reference to the magnitude of the cholesterol lowering effect of those substances may be made for foods falling within certain categories. According to those conditions, when reference is made to the magnitude of the cholesterol lowering effect, consumers are to be informed that plant sterols and/or plant stanol esters at daily intakes ranging from 1.5 to 2.4 g lower blood LDL-cholesterol by 7 to 10% within two to three weeks. Since new evidence has shown that an additional effect is achieved with higher intakes of those substances of up to 3 g per day, it was considered necessary to amend those conditions of use as regards the consumer information on the magnitude of the effect and the required daily intake, taking into account the scientific opinions of the European Food Safety Authority (EFSA).

The Commission informed the Committee that comments were submitted by the applicant of one of the two applications on the opinion of EFSA in relation to the scientific substantiation of the claim, namely the efficacy of the plant sterols versus the efficacy of the plant stanols, particularly with respect to intakes 2.5 – 3.0 g of plant sterols/plant stanols. EFSA, however, through technical assistance and correspondence, confirmed that it does not consider necessary to modify its conclusion on the scientific assessment (EFSA-Q-2012-01241) and confirmed that plant sterols and plant stanols at daily intakes ranging from 1.5 to 3 g have a similar efficacy on lowering blood LDL-cholesterol. Thus, and taking into account EFSA’s responses, the Commission, concluded that the Committee can proceed with the consideration of this draft measure. The Committee shared the Commission’s view; however, some Member States stated that if new evidence arises in the future about the efficacy of plant sterols/plant stanols, then the conditions of use of these claims should be reviewed.

In addition the Commission informed the Committee of a few editorial changes to the draft which aimed at making the text more consistent. A number of Member States expressed a preference for one single range of plant sterols/plant stanols intake (1.5 to 3 g), instead of the two ranges (1.5 to 2.4 g & 2.5 to 3 g) as proposed in the draft measure; nevertheless, all Member States could support the proposal as it was presented in the draft.

**Vote taken:** favourable opinion by unanimity (352 votes in favour).

**B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision authorising the placing on the market of coriander seed oil 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 coriander seed oil as a novel food in food supplements. On the basis of the discussion, a new recital 8 which refers to Directive 2002/46/EC and in Article 1 wording "without prejudice to the specific provisions of Directive 2002/46/EC" were added to the draft Decision.

**Vote taken:** favourable opinion by qualified majority (340 in favour, 12 abstentions).
B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision authorising the placing on the market of (6S)-5-methyltetrahydro-folic acid, glucosamine salt 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 (6S)-5- methyltetrahydro-folic acid, glucosamine salt as a source of folate in food supplements.

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

B.4 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision authorising the placing on the market of citicoline 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 citicoline in food supplements and in foods for special medical purposes. After a discussion it was decided to postpone the vote to further clarify in the draft decision that the use of citicoline is not intended for children.

B.5 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision authorising the placing on the market of rapeseed protein 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 rapeseed protein as a novel food ingredient. The proposal by one delegate to add to Article 3 of the draft decision a sentence "This statement shall appear in close proximity to the list of ingredients" was included in the text in addition to minor editorial changes.

**Vote taken:** favourable opinion by qualified majority (311 in favour, 41 abstentions).