Chair: Mr Basil Mathioudakis (for Items A1, A2, B1, B2, B3, C1 and C2)
Mrs Chantal Bruetschy (for Items C3 and C4)

All Member States were present except Bulgaria, Cyprus and Latvia.


A discussion took place on the basis of two documents submitted by Member States to the Standing Committee:

1) The document submitted by Ireland on the application of labelling and advertising restrictions of Directive 2006/141/EC to foods for special medical purposes (FSMPs) intended for infants as defined in Directive 1999/21/EC on dietary foods for special medical purposes (FSMP). In brief, the legal interpretation given in this document is that the labelling and advertising requirements of Directive 2006/141/EC do not apply to foods for infants falling under Directive 1999/21/EC on dietary foods for special medical purposes.

2) The informative e-mail sent by the French delegation where a different point of view was taken. They consider that given the vulnerable group of the population targeted (i.e. infants under medical supervision), all the provisions of Directive 2006/141/EC (e.g. on the use of pesticides, on labelling, advertising including claims) apply to foods for special medical purposes intended for infants, with the exception of the compositional requirements as laid down in point 4 of the Annex of Directive 1999/21/EC.

In the discussion that followed the following points were made:

- Products covered by Directives 2006/141/EC and 1999/21/EC are different and they are subject to distinct definition and denomination.

- Products covered by Directive 1999/21/EC are special products to be used when the dietary management of persons to whom they are intended "… cannot
be achieved only by modification of the normal diet, by other foods for particular nutritional uses, or by a combination of the two” (Definition of foods for special medical purposes). When Directive 1999/21/EC was discussed and adopted, FSMPs intended for infant from birth were very few, administered under medical supervision and usually distributed through pharmacies (particularly those of hospitals). As such they were not subject of promotional activities by the manufactures. Consequently, labelling, advertising and promotional restrictions, as those applicable to infant formula, were not considered appropriate at the time. Some such practices, for example the provision of samples of these products, were even considered useful in order to identify the product that would be most suitable or appropriate for the dietary management of the specific condition of the infant.

- It has to be admitted that the market situation has evolved since. Differing interpretation and enforcement of the definition of FSMPs by national authorities has contributed to a proliferation of these products in the market (the examples of products based on rice protein, not allowed for infant and follow-on formula, and of some anti-regurgitation products were mentioned). This in turn led to the use of wider and often similar distribution channels as those for infant formula and inevitably to labelling, advertising and marketing practices that were taking advantage of the absence of relevant rules for these products.

The Commission stressed the important role of the competent authorities in verifying the compliance of the products presented as FSMP with the relevant definition as laid down in Article 1 of Directive 1999/21/EC in order to avoid any abuse of the legislation.

On the basis of the discussion, and taking into consideration the letter of the law and the intention of the legislator when those measures were adopted, the Committee concluded the following:

Foods for special medical purposes intended specifically for infants, covered by the definition of Article 1 of Directive 1999/21/EC, are specific products and are distinct from infant formulae and follow-on formula. Therefore, foods for special medical purposes intended specifically for infants do not fall under the scope of Directive 2006/141/EC and are not subject to the provisions of that Directive except when specifically mentioned in Directive 1999/21/EC (see point 4 of the Annex of Directive 1999/21/EC).

Specific labelling requirements have been laid down in Directive 1999/21/EC taking into account the specificity of the product covered by that Directive (e.g. the medical conditions for which the product is intended, the mandatory statement on the label that the product must be used under medical supervision etc.). It is therefore not appropriate to apply the same labelling and advertising provisions as established in Directive 2006/141/EC to those products.

However, the Committee took note of the evolution in the market and considered that in the context of the revision of the framework legislation on foods for particular nutritional uses and acts thereof, further consideration should be given to the inclusion of certain relevant specific provisions for FSMPs.
A.2 Exchange of views of the Committee on a Polish notification of a draft Regulation amending the Regulation on the labelling of foodstuffs (2012/246/PL). The discussion will concern the paragraphs 1(5)(b) and 1(6) of the notified draft.

On 18 April 2012, the Polish authorities notified under the procedure of Article 19 of Directive 2000/13/EC a draft Regulation amending the Regulation on the labelling of foodstuffs.

The Polish delegation presented the notified measures and explained the reasons supporting additional labelling requirements with respect to bread baked from frozen dough and beer.

During the exchange of views, the delegations asked whether the above-mentioned measure should also apply to foods produced in other Member States and sold on the Polish market. Some delegations also questioned the compliance of the description "low-sugar" in names of fruit jams, jellies, preserves and sweetened chestnut purée, as provided in the notified draft, with the provisions of Regulation (EC) No 1924/2006 on nutrition and health claims made on foods.

The Polish authorities affirmed that the notified measure shall apply exclusively to foods produced in Poland undertakings belonging to the food sector with registered office in the Republic of Poland. Furthermore, they explained that the notion "low sugar", as laid down in § 1(8) of the notified text, is imposed for jams and jellies which have a soluble dry matter content of less than 60% in order to allow the consumer to distinguish such foods on the market. In this regard, it has been stressed that such product names are justified in the light of Council Directive 2001/113/EC relating to fruit jams, jellies and marmalades and sweetened chestnut purée intended for human consumption, whose Annex 1 stipulates that, without prejudice to Article 5(1) of Directive 2000/13/EC, Member States may authorise names for products having a soluble dry matter content of less than 60% for which sugars were replaced by sweeteners.

In accordance with the procedure laid down in Article 19 of Directive 2000/13/EC, the Commission will express its opinion regarding this notification taking into consideration this exchange of views.

B.1 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Regulation (EC) No 1924/2006 with regard to the list of nutrition claims. (SANCO/11221/2012)

A first draft Regulation benefited from a favourable opinion of the Standing Committee on 13 October 2011 but was opposed by a European Parliament resolution voted on 2 February 2012 because of the nutrition claim 'now contains 15% less [name of the nutrient]'. The new draft includes only the new claim ‘with no added salt’ and disqualifying criteria for the claim ‘light’. The new claim 'no added salt' would only be permitted if the natural content of sodium is low, i.e. below 0.12g sodium per 100g. Additional criteria to use the claim 'reduced in [name of the nutrient]' would be added to ensure such claims are not misleading:
- when saturated fat reduction is claimed, the criteria ensure that saturated fat is not replaced by trans fatty acids;

- for sugars reduction, the criteria ensure that the content in energy of the reformulated product is equal to or less than the content in energy in the original product, in order to avoid sugars substitution by fat.

During the exchange of views, several delegations requested clarifications regarding the possibility to use the claim 'no added salt' on foods containing constituents containing sodium. It was clarified that the conditions of use were excluding any addition of sodium/salt, directly or via an ingredient to which sodium/salt had been added, but that the presence of sodium in a food constituent naturally would not prevent the use of the claim provided the level of 0.12g sodium per 100g of final product was not exceeded.

**Vote taken:** The Committee delivered a favourable opinion by unanimity.

### B.2 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision concerning the draft Regulation on food and tobacco products and on amendments to certain related acts in respect of milled cereal products, pasta, bakery products, confectionery products and doughs. (SANCO/11067/2012)

On 19 January 2012, the Czech authorities notified a draft Regulation providing for additional labelling requirements for bakery and confectionary products. A negative opinion by the Commission was notified to the Czech authorities on 18 April 2012.

The draft Commission Implementing Decision provides that the Czech Republic shall refrain from adopting the measures requiring the mention “defrosted” and “from frozen semi-finished products” for the pre-packaged foods in question.

The Czech Republic informed the Committee that they withdrew the notified Regulation. It has been also pointed out that a modified text that took into account the Commission's negative opinion was submitted to the TRIS system. Consequently the draft Decision was not put to the vote.

### B.3 Exchange of views and possible opinion of the Committee on a draft Commission Regulation on the authorisation of a health claim made on foods and referring to the reduction of disease risk. (SANCO/10117/2012)

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 provided for in Article 14(1)(a) of that Regulation.

The Commission presented the draft and the health claim therein, including the relevant EFSA opinions. The Commission explained that given that two separate food business operators submitted similar applications aiming at authorising the same health claim referring to the reduction of a risk factor in the development of a disease, only one health claim in the draft is subject to such authorisation.
Both applications related to the effects of barley beta glucans on reduction of blood cholesterol, which is a risk factor in the development of coronary heart disease. In the light of a favourably assessed and subsequently authorised Article 14(1)(a) claim on oat beta glucans and reduction of blood cholesterol and other favourably assessed Article 13(1) claims on barley beta glucans and maintenance of blood cholesterol, the Commission proposed conditions of use which would ensure consistency with the other claims.

The Committee expressed no objections to the measure but due to procedural constraints the draft Regulation was not put formally to the vote.

**Vote taken:** The Committee delivered a favourable opinion by unanimity by written procedure on 4th July 2012.

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The draft Commission Regulation was not submitted to the Standing Committee at this stage due to the need of further discussions at expert level. However, a discussion took place on the aim of the draft, namely, authorising one health claim provided for in Article 14(1)(a) of that Regulation and relating to the effects of plant stanol esters on reduction of blood cholesterol, which is a risk factor in the development of coronary heart disease. Further, it would aim at amending the conditions of use of relevant authorised health claims relating to the effects of plant sterols and plant stanol esters on reduction of blood cholesterol, which is a risk factor in the development of coronary heart disease, authorised by previous decisions.

The Commission presented the relevant EFSA opinions which assessed namely the magnitude of the lowering effect of blood cholesterol with higher daily intakes of plant sterols and/or plant stanol esters than those already authorised by previous decisions. The Commission explained that the two applications raise a number of technical and legal issues that shall be addressed before a draft measure is submitted to the Committee. Therefore, those issues will be referred for further discussions at expert level and put to the vote of the Committee in a future meeting.

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**C.2 Exchange of views of the Committee on a draft Commission Regulation refusing to authorise a health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health. (SANCO11385/2012)**

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.
The application subject to this draft measure was based on newly developed scientific evidence and related to the effects of citrulline-malate on "maintenance of adenosite triphosphate (ATP) levels through reduction of lactates in excess for recovery from muscle fatigue".

The draft Regulation will be referred for further discussions at expert level and put to the vote of the Committee in a future meeting.


The aim of this draft new Decision is to provide for the choice between the long chemical name and the CAS No as a shorter designation of the novel chewing gum base in the list of ingredients.

It is planned to present the draft Commission Implementing Decision to SCFCAH (Section Toxicological Safety of the Food Chain) for an opinion on 11 July 2012.

C.4 Exchange of views of the Committee on a draft Commission Implementing Decision authorising the placing on the market of conjugated linoleic acid (CLA) as novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (Lipid Nutrition). (SANCO/10318/2011)

In spite of the additional information from Member States sent to EFSA in February 2012, EFSA, in their statement of 27 April 2012[1] concerning the safety of CLA as an ingredient to certain foods, confirmed in particular that "the safety of CLA consumption for periods longer than six months has not been established under the proposed conditions of use".

The Committee is aware that CLA is on the market in some Member States, as an ingredient to food supplements. In light of this and of the EFSA statement the Committee concluded that more information was needed to judge better the effects of CLA consumption and that it was therefore not appropriate to authorise the requested extension of use of CLA as ingredient to other foods at this point of time.