Chairmen:

Mr Basil Mathioudakis (for Items B1, B2, C1, C2, C3, C4, C5 and C6)

Mr Jose Luis De Felipe Gardon (for Items B3 and B4)

All Member States were present.

B.1 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision adopting guidelines for the implementation of specific conditions for health claims laid down in Article 10 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council.

The draft Commission Implementing Decision aims at adopting guidelines for the implementation of specific conditions for health claims provided for in Article 10 of Regulation (EC) No 1924/2006.

Article 10 of that Regulation foresees that the use of authorised health claims shall be permitted only if mandatory information foreseen in that Article is communicated to the consumer. It also foresees that food business operators have the possibility to use statements making reference to general benefits of a food for overall good health or health-related well-being if such general statements are accompanied by an authorised health claim from the lists of permitted health claims.

The Commission presented the draft Implementing Decision and a discussion took place on its last section, providing clarifications as to the possibility of operators to use statements for overall good health. One delegation noted that reference to general, non-specific benefits should be understood as comprising also statements mentioning a function of the body without further specification of a beneficial effect. The Commission noted the position and underlined that Article 10 sets rules as regards the context in which health claims are used and Member States should take that into account when controlling compliance with Article 10 of the Regulation.

Some delegations expressed the wish to clarify the condition for such statements to be "accompanied by" an authorised health claim in the sense that the health
claim should be 'next to' or 'following' the statement. The Commission agreed to revise the guidelines accordingly.

**Vote taken:** unanimous in favour.

### B.2 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending 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 draft Commission Regulation aims at amending Regulation (EU) No 432/2012 establishing the list of permitted Article 13(1) health claims by including twelve new health claims in the Annex of permitted health claims.

The Commission presented the draft and informed the delegations of the implications of the draft measure regarding the implementation of Regulation (EC) No 1924/2006, in particular with regard to the entries IDs in the consolidated list that would still remain 'on hold' after its adoption. These include claims on 'botanical' substances where the reflection initiated by the Commission is still ongoing and claims that may be affected by the revision of the legislation on foodstuffs for particular nutritional uses.

In light of numerous comments from the Member States of both editorial and substantial nature and the need to further clarify some issues raised, the Committee was not requested to give its opinion on the draft, which will be referred to for final discussions at experts group and submitted to the Committee at a future meeting.

There was a lengthy discussion on certain claims subject to the measure as outlined below:

**Claims on caffeine:** The Commission took note of the concerns expressed for the five claims on caffeine. It noted that the main concerns of Member States differ between the two claims on caffeine and concentration and alertness addressed to the general population and the three claims targeting adults performing endurance exercise. For the first type of claims, it is understood that some delegations question the validity of the warning, in the sense that the value of safe daily intake proposed (notably 300 mg) and which derives from a report of the SCF 1999, is outdated and should be modified after taking into account more recent studies. For the second type of claims, the Commission takes account of the concerns of a number of delegations in relation to the potential health risks of caffeine consumption for people performing exercise. Accordingly, the Commission agreed, on the basis of the concerns raised for all health claims related to caffeine, to refer the matter back to EFSA for advice before those claims are authorised.

**Claims on carbohydrates:** The majority of the delegations raised serious concerns for this health claim, considering it confusing for the consumer in light of national dietary advice to reduce sugar consumption, despite EFSA's favourable scientific assessment and the efforts of the Commission to clarify the food subject to the claim. Some Member States suggested modifications to the conditions of use of the claim to take account of these concerns. The Commission will therefore reflect
further on the conditions of use in order to find a satisfactory solution which would enable the authorisation of the claim.

Claims on EPA/DHA: Several delegations agreed to the clarification of the condition of use of the claims with regard to information to consumer not to exceed a supplemental daily intake of 5g of DHA and EPA combined, as proposed by two delegations in order to reflect more accurately EFSA’s scientific advice.

Claim on fructose: Some delegations raised concerns about the claim as they considered it confusing for the consumer in light of national dietary advice to reduce sugar consumption and this despite EFSA’s favourable scientific assessment. The Commission provided explanations to support the acceptance of the claim under the stated conditions of use for the consideration of the Member States.

B.3 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision authorising an extension of uses of Chia (Salvia hispanica) seed as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council.

Some editorial amendments were agreed. And in particular, in Article 2 the wording of the additional labelling requirements concerning pre-packaged Chia was simplified.

Vote taken: unanimous in favour.


Some editorial amendments were agreed. And, in particular, the recitals need to reflect that as a result of the initial assessment an additional assessment was required and that the applicant in response to the additional assessment and comments from other Member States limited his request to the use of synthetic zeaxanthin in food supplements with a maximum intake of 20 mg per person per day, initially. It was also agreed to add the word synthetic to the labelling of zeaxanthin, i.e. ‘synthetic zeaxanthin’.

Vote taken: unanimous in favour.

C.1 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.

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 provided for in Article 13(5) of that Regulation. The application related to the effects of EffEXT™ and “helps to support joint function by maintaining low levels of plasma C-reactive protein”.
The draft Regulation will be referred for further discussions at expert level and put to the vote of the Committee in a future meeting.


As provided for in Article 18(4) of Regulation (EC) No 1924/2006 Member States were consulted on one health claim provided for in Article 13(5) of that Regulation, which received a favourable assessment from the European Food Safety Authority (EFSA). The health claim related to the effects of cocoa flavanols and maintenance of normal endothelium-dependent vasodilation.

The Commission presented the draft Commission Decision. Member States and the Commission agreed to authorise the claim with a wording which is more understandable to consumers by making reference to the 'maintenance of the elasticity of blood vessels'. In addition, as regards the wording of the claim to be authorised, all delegations that intervened, expressed their preference that the wording of the claim should refer to 'normal blood flow' as proposed by EFSA and not to a 'healthy blood flow' as requested by the applicant.

Two delegations raised some concerns regarding the setting of appropriate conditions of use. In particular, a discussion took place on whether there is a need to further specify cocoa beverages (water or milk based) and define dark chocolate. A couple of MS noted that such health claim might be promoting consumption of products in a way that is against national dietary advice and health policies.

The comments expressed during that discussion will be taken into account by the Commission before finalising its decision authorising the claim.


As provided for in Article 18(4) of Regulation (EC) No 1924/2006 Member States were consulted on one health claim provided for in Article 13(5) of that Regulation, which received a favourable assessment from the European Food Safety Authority (EFSA). The health claim related to the effects of slowly digestible starch and reduction of postprandial glycaemic responses.

The Commission presented the draft Commission Decision. A discussion took place on the two possible options for wording submitted to the Member States. The majority of the delegations that intervened, expressed their preference for a wording that would ensure consistency with a similar Article 13(1) authorised health claim which refers to "induces a lower blood glucose rise after a meal".

One delegation raised serious concerns against the authorisation of this health claim because it considers that the definition of the food subject to the claim,
namely "slowly digestible starch", is unclear and not based on a widely used method. The Commission noted that since the food is well characterised according to EFSA and given that food operators using the claim have the responsibility to demonstrate compliance with its conditions of use, the claim should be authorised for use.

The comments expressed during that discussion will be taken into account by the Commission in finalising its decision authorising the claim.

**C.4 Discussion and agreement on Draft Guidance Document for Competent Authorities for the Control of Compliance with EU Legislation on:**


The Commission presented the draft guidance document. Delegations that intervened welcomed and generally supported the draft guidance. They highlighted the importance to gather experience in practice; based on such experiences, the guidance could be updated in the future if necessary. Some delegations asked the Commission for a translation of the guidance to all Union languages; the Commission agreed to look into the matter but due to tight capacities for translation there would be a low priority for non-legislative texts. Some Member States noted few editorial suggestions, noted the importance to check examples carefully for correctness, suggested to re-discuss the rounding rules proposed for energy in the future, asked for a summary table of all tolerance values which was seen as helpful, as well as asked for a more detailed explanation.
about the cases where section 5.4 would be applied. All these issues noted by Member States were not seen as crucial and could therefore be addressed in the future if an update of the guidance would be considered. The Commission informed Member States that it would draft a summary table of tolerance values in the guidance and make this available in the DG SANCO relevant website together with the guidance. One delegation asked for clarification about a concrete upper tolerance value for vitamin C in liquid, the Commission explained that this would be up to each Member State to identify, and should there be a need to harmonise the approaches across the EU in the future, a value could be discussed and included in an updated version of the guidance document. Some concerns were raised by one delegation regarding the recommendation for a smooth transition which should end at the latest on 13 December 2014 and the compatibility of this recommendation with transition periods identified in Regulation (EU) No 1169/2011. The Commission explained that the guidance document is not a legislative text, it provides guidance for the control of the nutrition declaration regardless of the legal regime that the nutrition declaration complies with (Directive 90/496/EEC or the new Regulation (EU) No 1169/2011). Therefore, the guidance would not interfere with Regulation (EU) No 1169/2011.

The German representative supported the draft guidance document and the principles it is based on, but noted that they were still in the process of seeking advice from their control authorities with regard to section 5.

In conclusion, the draft guidance document met with broad, general support. The Commission called on Member States to provide feedback about their experiences when applying the guidance in the coming years. Based on such feedback a review of the guidance would be considered, if necessary.


The Commission presented the draft guidance document. A number of delegations welcomed and supported the draft guidance, but noted that not all methods listed in the document were currently used by the national control authorities and due to limited resources not all methods may be established. One delegation explained that one of the methods listed is currently reviewed and an improved version may be available in the future. The Commission noted that there are a number of methods included in the draft guidance document and cross-border trade problems due to the application of different methods that are used in different countries should not arise. If necessary, the guidance document could be reviewed in the future.

In conclusion, the draft guidance document met with broad, general support. The Commission will remain vigilant about the need to review the guidance.

C.6 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. It would refuse to authorise the use of four 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:
• “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

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

A discussion took place on the period of six months granted to food business operators and Member States to adapt to the rejection of health claims referred to in Art. 13(5) and 14(1)(b) of Regulation (EC) No 1924/2006 in case such claims are still used at the moment of the adoption of the measure rejecting their use.

Member States and the Commission discussed extensively the issue and agreed that once the Regulation (EU) No 432/2012 establishing the list of permitted health claims becomes applicable, i.e. 14 December 2012, no claims other than those authorised or placed 'on-hold' during the establishment of the list of permitted health claims or for which an individual application for authorisation was submitted before 19 January 2008 in accordance with Article 28(6) of Regulation (EC) No 1924/2006 can remain on the market.

Given the new legal framework and taking into account that Article 13(1) health claims which are 'on hold' can still remain on the market after 14 December 2012 and would benefit from a six months period if a decision is taken on their insertion
in the list of non-authorised claims, it was decided that the same approach would be proportionate and pragmatic also for Article 13(5) claims which are considered as 'on hold' on the date of 14 December 2012, in the sense that an application for authorisation is submitted before that date and a decision to their regard is pending.

It was clarified that this would apply only for applications submitted to the national competent authorities before 14 December 2012 insofar they are validated and subsequently transmitted to EFSA for assessment. It is also considered appropriate to treat all claims subject to the individual procedures in a coherent manner and apply the same approach for Article 14(1)(b) claims as well. In light of the above, the Commission and the Member States agreed to share information in order to draw the list of all claims subject to the individual authorisation procedure which are considered as 'on hold' on the date of 14 December 2012.

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

M.1 Implementation of Regulation (EU) No 432/2012

In view of the forthcoming date of application of Regulation (EU) No 432/2012 establishing the list of permitted health claims, namely 14 December 2012, the Commission asked Member States to provide information on the progress of the implementation of that Regulation by national controlling authorities. The aim is to ensure the correct and coherent implementation across the EU of the new legal framework as regards the use of health claims. The Commission noted that such information would be useful in view of the requirement of Article 27 of Regulation (EC) No 1924/2006 on nutrition and health claims for the Commission to submit to the European Parliament and the Council a report on the application of that Regulation. Nevertheless, details as to the type and the modalities of the information to be provided by Member States in view of that report would be agreed in the future.