SUMMARY REPORT OF THE
STANDING COMMITTEE ON THE FOOD CHAIN AND ANIMAL HEALTH
HELD IN BRUSSELS ON 13 JUNE 2014
(Section General Food Law)

A.01 Exchange of views of the Committee on a Working document prepared by the Commission services for consultation of Member States on 4 health claims related to "Complex carbohydrates and contribute to satiety" (Question No EFSA-Q-2008-131), "Choline and development of brain" (Question No EFSA-Q-2008-134), "Zinc and normal function of the immune system" (Question No EFSA-Q-2008-189) and "CranMax® and reduction of the risk of urinary tract infection" (Question No EFSA-Q-2013-00649) pursuant to Regulation (EC) No 1924/2006 (Art. 14(1) of Regulation (EC) No 1924/2006) (Regulatory procedure with scrutiny)

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) of that Regulation, for which the European Food Safety Authority (EFSA) published its opinions on 5 May 2014. More specifically, the applications subject to this working document related to the effects of:

- Zinc and normal function of the immune system (favourable opinion)
- Choline and development of brain
- Complex carbohydrates and contribute to satiety
- CranMax® and reduction of the risk of urinary tract infection

With regard to the claim on zinc, one Member State considered that the authorisation of such health claim may be premature considering that the discussions in the context of the implementation of Regulation (EU) No 609/2013 on foods for specific groups are still on-going, in particular with respect to the update of the compositional requirements for these foods.

The comments expressed during that 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.02 Exchange of views of the Committee on a Working document prepared by the Commission services for consultation of Member States on 6 health claims related to "A combination of LA101, LA102, LA103 and LA104 and stool
frequency" (Question No EFSA-Q-2013-00893), "A combination of LA101, LA102, LA103 and LA104 and intestinal discomfort" (Question No EFSA-Q-2013-00892), "Pacran® and defence against bacterial pathogens in the lower urinary tract" (Question No EFSA-Q-2013-00889), "Olive leaf water extract and increase in glucose tolerance" (Question No EFSA-Q-2013-00783), "Cocoa flavanols and endothelium-dependent vasodilation" (Question No EFSA-Q-2013-00832) and "Citrulline-malate and faster recovery from muscle fatigue after exercise" (Question No EFSA-Q-2013-00659) pursuant to Regulation (EC) No 1924/2006 (Art.13(5) of Regulation (EC) N° 1924/2006)

Member States were consulted on six health claims submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, for which the European Food Safety Authority (EFSA) published its opinions on 5 May 2014. More specifically, the applications subject to this working document related to the effects of:

- A combination of LA101, LA102, LA103 and LA104 and stool frequency
- A combination of LA101, LA102, LA103 and LA104 and intestinal discomfort
- Pacran® and defence against bacterial pathogens in the lower urinary tract
- Olive leaf water extract and increase in glucose tolerance
- Cocoa flavanols and endothelium-dependent vasodilation (favourable opinion)
- Citrulline-malate and faster recovery from muscle fatigue after exercise

There were no comments from the Member States with respect to the above opinions. The matter will be referred for further discussion at expert's level.

**B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) on the requirements for the provision of information to consumers on the absence or reduced presence of gluten in food (Art. 36(3) of Regulation (EU) No 1169/2011) (SANCO/10123/2014)**

The draft implementing Regulation will transfer under Regulation (EU) No 1169/2011 on the provision of food information to consumers the rules on the use of the statements "gluten-free" and "very low gluten", currently set in Regulation (EC) No 41/2009 on foodstuffs suitable for people intolerant to gluten. The Commission recalled that Regulation (EC) No 41/2009 will be repealed as of 20 July 2016 by Regulation (EU) No 609/2013 on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control. During the negotiations on Regulation (EU) No 609/2013 it was agreed that the rules of Regulation (EC) No 41/2009 should be maintained under the framework of Regulation (EU) No 1169/2011.

The Commission presented the draft implementing Regulation that follows as closely as possible the requirements of Regulation (EC) No 41/2009. In addition, the draft measure specifies how operators can inform the targeted group of consumers of the difference between foods that are naturally free of gluten and products that are specifically formulated for them. The Commission recalled that this provision addresses the concerns, raised by the co-legislators during the negotiations on Regulation (EU) No 609/2013, that the abolition of the concept of "dietetic food", and more specifically of "food for people intolerant to gluten", would result in less information for the targeted group of consumers about the different products being available to them.
The Commission asked the delegations to ensure that the different linguistic versions of the draft Regulation, in particular with respect to the definition of "gluten", were carefully checked and to provide linguistic comments to the Commission if necessary. The Committee welcomed the draft and noted that it respects the inter-institutional agreement reached during the negotiations of Regulation (EU) No 609/2013. Two delegations noted that foods covered by Regulation (EC) No 41/2009 are today accompanied, in certain cases, by the statement "suitable for coeliacs" instead of the statement "suitable for people intolerant to gluten". Those delegations asked to amend the draft implementing Regulation to allow the use of the statement "suitable for coeliacs", as an alternative. One delegation expressed its concerns that the possibility to use this alternative statement would result in confusion for consumers. The Commission recalled that the draft implementing Regulation is aimed at transferring existing rules. Taking into account that the statement "suitable for coeliacs" is currently used in certain Member States in line with Regulation (EC) No 41/2009, and no concern has been reported about its use, its prohibition through the draft implementing Regulation would not be justified. In this context, it was also noted that the additional statement is supported by the relevant stakeholders, including coeliac associations. The Committee eventually agreed to amend the draft in order to allow the use of the statement "suitable for coeliacs" as an alternative to the statement "suitable for people intolerant to gluten". The Committee also agreed, in order to ensure consistency, to allow the statement "specifically formulated for coeliacs" as an alternative to the statement "specifically formulated for people intolerant to gluten".

Two delegations asked to modify the conditions for the use of the statements "suitable for coeliacs / suitable for people intolerant to gluten" when used together with the statement "very low gluten". This request was not supported by other delegations. One delegation noted that the statements "suitable for coeliacs" / "suitable for people intolerant to gluten" are health claims and should be covered by Regulation (EC) No 1924/2006. The Commission recalled that this point was considered during the negotiations on Regulation (EU) No 609/2013. The decision as to how to deal with those statements was agreed by the co-legislators then and any discussion on this point would not be possible in the context of the draft implementing Regulation. Two delegations asked whether logos currently used together with statements indicating the absence of gluten in food would be allowed under the new draft implementing Regulation. One of these delegations noted that logos should be used only alongside such statements and not as an alternative to them. The Commission clarified that the use of logos is currently out of the scope of Regulation (EC) No 41/2009. The Committee agreed that logos will not be covered by the new draft implementing Regulation and agreed on a drafting change in this respect. On the basis of comments raised by two delegations, the Committee agreed to modify one recital to further clarify that the conditions to use the statement "gluten-free" apply to all foods, including those naturally free of gluten, and a footnote to another recital to improve the reference to the Codex Standard for foods for special dietary use for persons intolerant to gluten.

Vote taken: favourable opinion

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) refusing to authorise certain health claims made on foods, other...

This draft Commission Regulation was submitted to the Standing Committee in accordance with Article 18(5) of Regulation (EC) No 1924/2006. This draft measure aims at refusing to authorise the use of eight health claims foreseen in Article 13(5) of that Regulation. The applications for authorisation of these health claims were based on newly developed scientific evidence as provided for in Article 13(5) of the same Regulation. The Commission presented the draft and the health claim therein.

In relation to the claim on zinc and bad breath, the Commission recalled that, in the context of claims submitted pursuant to Article 13(1) of Regulation (EC) No 1924/2006, claims on the maintenance of normal structure, elasticity, appearance and tonicity of the skin or claims on the maintenance of normal structure and appearance of hair and nails were evaluated on a case-by-case basis and they were not authorised, by virtue of Commission Regulation (EU) No 536/2013, because on the basis of the scientific evidence submitted, the European Food Safety Authority (EFSA) concluded that the claimed effect did not refer to a function of the body, as required by the Regulation. For example, in different cases EFSA noted:

- that the evidence provided did not refer to a particular physiological function of the skin, or
- that the evidence provided did not establish that changes in the appearance or elasticity or tonicity of the skin relate to changes in skin function, or
- that the maintenance of normal structure and appearance of hair and nails did not refer to a function of the body.

Nevertheless, the Committee agreed that Member States should assess claims on a case-by-case basis, and decide whether their wording (or claimed effect) states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health, and therefore as falling under the scope of Regulation (EC) No 1924/2006. Where this is not the case, still the claim should respect the general provision that the labelling, presentation or advertisement should not mislead the purchaser by attributing to the foodstuff effects or properties which it does not possess (Article 2(1)(ii) of Directive 2000/13/EC).

With respect to the health claim related to the effects of Lactobacillus rhamnosus GG and maintenance of normal defecation during antibiotic treatment (Q-2013-00015), there was a discussion with the Member States regarding the acceptability of applications for authorisation of claims which target groups under medical treatment and which relate to side effects of the treatment. The Committee noted that a preliminary analysis of the claim is necessary in order to determine whether such a claim should be evaluated within the scope of Regulation (EC) No 1924/2006. Such analysis will have to be carried out on a case-by-case basis by the Member States. In that context, the Commission also made reference to EFSA's General guidance for stakeholders on the evaluation of Article 13(1), 13(5) and 14(1) health claims, which states that the population group for which health claims are intended is the general (healthy) population or specific subgroups thereof, for example, elderly people, physically active subjects, pregnant women, etc.

The Commission recalled that there are numerous occasions for exchange with the Commission services and those of EFSA where necessary.

**Vote taken: favourable opinion**
B.03 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) 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) (SANCO/10371/2013)

This draft Commission Regulation was submitted to the Standing Committee in accordance with Article 18(5) of Regulation (EC) No 1924/2006. This draft measure aims at refusing to authorise the use of seven health claims foreseen in Article 13(5) of that Regulation. The applications were based on newly developed scientific evidence and for all of them the applicants requested the protection of proprietary data, as provided for in Article 13(5) of the same Regulation.

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

Vote taken: favourable opinion

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) on the authorisation of a health claim made on foods and referring to the reduction of disease risk (Art. 14(1) of Regulation (EC) No 1924/2006) (SANCO/12574/2013)

This 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 on monounsaturated and/or polyunsaturated fatty acids and the reduction of LDL-cholesterol concentrations, pursuant to Article 14(1)(a) of Regulation 1924/2006. The European Food Safety Authority (EFSA) gave a favourable opinion to this claim and accordingly it should be authorised. In the presentation of this draft the Commission mentioned comments it had received from an interested stakeholder in relation to this health claim and the proposed conditions of use.

There were no comments or observations by the delegations.

Vote taken: favourable opinion

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) authorising and refusing to authorise certain health claims made on foods and referring to the reduction of disease risk (Art. 14(1) of Regulation (EC) No 1924/2006) (SANCO/10121/2014)

This 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 three health claims while rejecting five health claims, pursuant to Article 14(1)(a) of Regulation 1924/2006. The Commission presented the draft and the health claim therein.

With regard to the three claims to be authorised, one Member State raised concerns about the need to have two different references in relation to the target population
when using two health claims, namely, the one calcium and vitamin D and the other one on vitamin D alone, on the same product. While the use of both claims on the same product will comply with the conditions of use set out for each of these claims, it will be difficult to target two different populations, women over 50 on the one hand and men and women over 60 on the other hand. It was noted that the two claims, and the respective conditions of use, had been submitted by different operators and that their simultaneous use on the same product was not likely.

Vote taken: favourable opinion


The Commission presented the draft Implementing Decision to authorise an extension of use of DHA-rich oil from the micro-algae Schizochytrium sp as a novel food ingredient. As two previous authorisation decisions have been already adopted on the same novel food and addressed to the same applicant, the draft Decision also consolidates all previous authorisations and therefore replaces the previous Decisions 2003/427/EC and 2009/778/EC.

One Member State proposed to amend the name of the novel food to "oil from the micro-algae Schizochytrium sp" in the draft document in order not to prejudice the rules on nutrition and health claims in Regulation (EC) 1924/2006. This is also in line with the previous Decision 2009/778/EC. One Member State also proposed to delete the word "nutrition" from the food category "cereal bars" as it was considered unclear what type of food this is referring to.

The Committee accepted these proposed changes, but UK requested it to be noted in the minutes of the meeting that they supported the original text on the draft Implementing Decision.

Vote taken: favourable opinion