#### EUROPEAN COMMISSION



HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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### SUMMARY REPORT OF THE STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED HELD IN BRUSSELS ON 04 NOVEMBER 2015

(Section General Food Law)

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A.01 Presentation by the Commission of the roadmap on the evaluation of a) Regulation (EC) No 1924/2006 on nutrition and health claims made on food with regard to nutrient profiles and health claims made on plants and their preparations and of b) the general regulatory framework for their use in foods.

The roadmap paving the way for the evaluation of certain aspects of the Regulation on nutrition and health claims was presented.

The evaluation will examine whether nutrient profiles provided for in the Regulation, which have not yet been adopted, are warranted and adequate to ensure the objectives of the Regulation. These nutrient profiles are thresholds of nutrients such as fat, salt and sugars above which nutrition and health claims are restricted, thus preventing a positive health message on food high in these nutrients.

The evaluation will also examine whether the current rules concerning health claims on plants and their preparations used in foods are adequate, and how the use of such claims interacts with the current applicable food regulatory framework on plants and their preparations.

The evaluation will include one open public consultation, which will run for a period of 12 weeks and also one stakeholders' consultation specifically targeting SMEs, which will run for a period of 8 weeks. Both will be launched in the second half of 2016. The final report and action plan are expected beginning of 2018.

Several Member States regretted that this evaluation would further delay the setting of nutrient profiles, while some also called for further harmonisation in the area of the use of plants and their preparations in foods. It was also questioned whether the evaluation would replace the report on the application of the Regulation referred to in Article 27 of Regulation (EC) No 1924/2006.

The Commission acknowledged that free circulation of foods containing plants or plant extracts could be improved, as the principle of mutual recognition was not properly working in that area. The evaluation exercise will allow for a mapping of these problems and help identifying solutions to them. Its results will feed into the report referred to in Article 27 of Regulation (EC) No 1924/2006 but not replace it.

#### A.02 Update by the Commission on the state-of-play of the Fitness Check on Regulation (EC) No 178/2002 on General Food Law.

The Commission presented an update on the state of play of the Fitness Check on Regulation (EC) No 178/2002 on General Food Law (GFL) Regulation. As a preliminary remark, it was clarified that a fitness check is a comprehensive policy evaluation assessing whether the regulatory framework for a policy area is fit for purpose. Because of its nature, a Fitness Check is capable of unearthing overlaps, gaps, inconsistencies, obsolete measures and excessive burdens, while exploring whether there is scope for simplification.

The GFL Regulation was chosen precisely because it is the cornerstone of the EU food and feed policy. The criteria to be covered are efficiency, EU added value, coherence, effectiveness and relevance.

For the purpose of this Fitness Check, the Commission commissioned two external studies: one on the general provisions of the GFL Regulation and one on the RASFF/crisis management. As far as EFSA is concerned, the Commission will reply on the last external evaluation of 2012, as recently updated in collaboration with EFSA and the Member States. Other relevant information will also be taken into account.

The findings of the two studies were presented to the members of the Committee. The Commission also made clear that this evidence would need to be synthesised and triangulated with other available information and studies.

The fitness check exercise of the GFL Regulation is expected to be completed in the 1<sup>st</sup> quarter of 2016 by means of a Commission Staff Working Document.

### A.03 Exchange of views of the Committee on a French notification (2015/364/FR) of a draft Order defining the list of substances authorised in food supplements for nutritional or physiological purposes and the conditions for their use.

On 9 July 2015, the French authorities notified under the procedure of Article 12 of Regulation (EC) No 1925/2006 a draft Order defining the list of substances authorised in food supplements for nutritional or physiological purposes and the conditions for their use.

The French delegation presented the draft measure that provides *inter alia* for a list of substances for nutritional or physiological purposes other than vitamins and minerals that are authorised for use in food supplements, and that establishes recommended daily servings for four substances that include caffeine, carnitine, creatine and lycopene. The French delegation explained that the recommended daily servings for these four substances are based on scientific opinions adopted by the European Food

Safety Authority (EFSA), and that the French Decree No 2006-352 of 20 March 2006 lays down the general rules that are applicable for the use of other substances in the manufacture of food supplements.

During the exchange of views, a delegation sought clarifications with regard to the application of Article 5 (2) of the notified draft measure that refers to the dose at which the desired physiological or nutritional objective is achieved, to those substances listed in Annex I to the notified draft for which a recommended daily serving has been set. In reply, the French delegation agreed to modify the provision so as to make it clear that Article 5 (2) applies without prejudice to the provisions laid down by Article 5(1).

Some Member States took the opportunity to underline the need to harmonise the use of other substances in foods and food supplements. A delegation proposed the use of the procedure under Article 8 of Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods, to lay down harmonised conditions of use for the use of these four substances in foods. The Commission took note of the delegations' comments.

In accordance with the procedure laid down in Article 12 of Regulation (EC) 1925/2006, the Commission will express its opinion regarding this notification taking into consideration this exchange of views.

# A.04 Exchange of views of the Committee on a Romanian notification (2015/152/RO) of a draft Order of the Ministry of Agriculture and Rural Development and the Ministry of Health with regard to the preparation, processing and marketing of medicinal and aromatic plants used on an "as is" basis, which are partially processed or processed as pre-dosed food supplements.

On 31 March 2015, the Romanian authorities notified a draft Order of the Ministry of Agriculture and Rural Development and the Ministry of Health with regard to the preparation, processing and marketing of medicinal and aromatic plants used on an "as is" basis, which are partially processed or processed as pre-dosed food supplements. An exchange of views on the notified measure was held during the meeting of the Standing Committee on Plants, Animals, Food and Feed (PAFF Committee) of 9 June 2015. Following the comments received by the Commission and by the other Member States, the Romanian authorities revised the notified draft measure and were therefore invited to present this revised draft to the PAFF Committee.

During the exchange of views, certain delegations asked the Romanian delegation for clarifications regarding the inclusion of certain plants in the positive list of the notified draft measure that are currently not permitted for use in food supplements in some other Member States. The Romanian delegation informed the Committee that replies to these questions would be sent through the TRIS system. A delegation took the opportunity to highlight the need to harmonise the use of plants and their preparations in foods and food supplements.

The Commission brought to the attention of the Romanian delegation that the use of term "medicinal plants" in the notified draft measure could be misleading with regard to the intention of the notified draft Order

The Commission reminded the Romanian delegation that the revised version of the draft measure must be sent to the Commission and to the other Member States through the TRIS system and that the standstill period of 6 months will start only after such notification has been done. In accordance with the procedure laid down in Article 12 of Regulation (EC) 1925/2006, the Commission will express its opinion regarding this notification taking into consideration this exchange of views.

#### A.05 Exchange of views of the Committee on a Lithuanian notification (2015/465/LT) of a draft Order on mandatory origin indication of milk and milk used as an ingredient in certain milk products.

On 6 August 2015, the Lithuanian authorities notified under the procedure of Article 45 of Regulation (EU) No 1169/2011 a draft Ministerial Order entitled "Requirements for the declaration of the country of origin of milk used as an ingredient in milk and milk products".

The Lithuanian delegation presented the notified draft and briefly explained the reasons supporting additional labelling requirements. It was clarified that the draft Regulation intends to serve the high consumer expectation in Lithuania to see a declaration of country of origin on milk and milk products. Lithuania informed that they intended to send a reply to the Commission's detailed opinion.

Some Member States commented on the notification. The Member States that spoke where opposing to the notification. Some found that the notified national measures were in conflict with Article 34 of the Treaty and that they evoked possible barriers to trade. Some said that the information provided by Lithuania did not justify the imposed national provisions under Regulation (EU) No 116/2011, Article 39.

The Commission explained the notification procedure under Regulation (EU) No 1169/2011 and commented briefly on the Lithuanian notification. The Commission informed that the justifications provided by Lithuania did not fulfil the requirements of Article 39 and therefore an official letter had been sent to Lithuania asking for further justification. On the basis of the reply and in line with the procedure laid down in Article 45, the Commission will assess the notification.

# A.06 Exchange of views of the Committee on a Working document prepared by the Commission services for consultation of Member States on one health claim related to "Equazen eye q® and improving reading ability" (Question EFSA No Q-2014-00462) 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 one health claim provided for in Article 14(1) of that Regulation, for which the European Food Safety Authority published its opinions on 13 October

2015. More specifically, the application subject to this working document related to the effect of: "Equazen eye q® and improving reading ability".

The Commission presented the working document and the health claim therein. No comments were raised by the delegations with respect to the above claim. The matter will be referred for further discussion at expert's level.

# A.07 Exchange of views of the Committee on a Working document prepared by the Commission services for consultation of Member States on one health claim related to "Lactitol and the maintenance of normal defecation" (Question EFSA No Q-2015-00375) pursuant to Regulation (EC) No 1924/2006 (Art. 13(5) of Regulation (EC) No 1924/2006).

Member States were consulted on one health claim submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, for which the European Food Safety Authority (EFSA) published its opinions on 13 October 2015. More specifically, the application subject to this working document related to the effects of: "Lactitol and the maintenance of normal defecation".

Some Member States raised concerns as regards the laxative effect of lactitol. It was argued that the wording to be authorised should make clear the laxative effect of the food to consumers. Concerns were also raised in relation to the marketing of lactitol under different pieces of EU legislation concerning lactitol (e.g. Food Information to Consumers or legislation on additives). Lastly, one Member State expressed concerns in relation to the recommended dose by EFSA and the type of foods that would eventually bear such a claim.

The comments expressed by the delegation 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.

## B.01 Exchange of views and possible opinion 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.

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 five health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health, pursuant to Article 13(5) of Regulation (EC) No 1924/2006.

The European Food Safety Authority (EFSA) gave an unfavourable opinion to these health claims and accordingly they should not be authorised. The Commission presented the draft and the health claims therein. There were no comments or observations by the delegations.

Vote taken: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Regulation refusing to authorise a health claim made on foods and referring to the reduction of disease risk.

This draft Commission Regulation was submitted to the Standing Committee in accordance with Article 17(3) of Regulation (EC) No 1924/2006. It aims at refusing to authorise one health claim made on foods and referring to the reduction of disease risk, pursuant to Article 14(1)(a) of Regulation (EC) No 1924/2006.

The European Food Safety Authority (EFSA) gave an unfavourable opinion to this health claim and accordingly it should not be authorised. The Commission presented the draft and the health claim therein. There were no comments or observations by the delegations.

**Vote taken:** Favourable opinion.

C.01 Exchange of views of the Committee on a draft Commission Regulation authorising a health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health and amending Regulation (EU) No 432/2012.

As provided for in Article 18(4) of Regulation (EC) No 1924/2006 Member States were consulted on one health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health, related to native chicory inulin and bowel function. The claim was submitted pursuant to Article 13(5) with a request for protection of proprietary data.

The European Food Safety Authority (EFSA) gave a favourable opinion to this health claim and accordingly it should be authorised. The Commission presented the draft Regulation authorising the claim in question granting protection of proprietary data. There were no comments or observations by the delegations on this draft measure.

Further to this exchange of views and the consensus of the Member States, the Commission will continue with the authorisation of this claim.