



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 12 APRIL 2016
(Section General Food Law)**

CIRCABC Link: <https://circabc.europa.eu/w/browse/7d17a6c7-c0a2-48d1-b7be-8df54fe4a72b>

A.01 Exchange of views on the French notification of the draft Decree related to the origin indication of milk and meat used as an ingredient (AGRAP/2016/0339 - projet de décret relatif à l'indication de l'origine du lait et des viandes utilisées en tant qu'ingrédient).

The French delegation provided a presentation of the draft decree which introduces origin labelling obligations for milk, food containing milk products and food containing meat. These labelling rules would only apply to food produced in France and, in a first stage, for a period until 31 December 2018. Before the end of this period, France would provide a report which would allow for an opportunity to review data on consumer interest and willingness to pay, and on the potential impact on the internal market.

During the subsequent discussion, a number of Member States raised concerns relating to the negative impact of the French measure on the access of non-French ingredient suppliers, particularly SMEs, to food production and distribution in France. They questioned the link between the quality of the foods concerned and their origin and expressed a preference for voluntary origin information and existing food quality schemes. They also expressed concerns relating to the disproportionately high costs that would result from a pilot project, also in view of possible detrimental effects as regards food waste.

Other delegations did not oppose mandatory origin indication as such, but expressed a preference for a harmonised approach at EU level, while a few delegations supported the French draft decree.

The Commission recalled that the EU food information rules allow Member States to adopt national measures in the field of origin information on food under certain substantial and procedural conditions. It also stressed that the topic was intensively debated at the co-decision stage and that the political and legal context has significantly evolved in recent years.

A.02 Exchange of views on the Irish notification of the draft Bill related to sale, labelling, advertising, marketing, and display of alcohol products (2016/0042/IRL).

The Irish draft bill provides for a comprehensive set of measures, which include mandatory health warnings and the indication of energy values on labels.

Ireland stressed that the objective of the measures was to tackle an extremely high consumption of alcohol at national level, with significant consequences for public health. Its intentions were in line with the WHO Global strategy to reduce harmful use of alcohol. The Food Information Regulation did not prevent national measures, particularly since the Commission had so far not acted on the matter.

Several Member States acknowledged the public health objective pursued by Ireland but expressed their concerns related to the market access of alcoholic beverages from other Member States to Ireland, to the proportionality of the measure and to a national initiative in an area where a harmonised approach should be taken at EU level.

A few Member States were supportive of the draft. In particular, they welcomed the obligation to provide a nutrition declaration. A few Member States welcomed the concept of the Irish initiative, but expressed their preference for a harmonised approach at EU level, while calling for the Commission report on the issue.

A.03 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 "Creatine in combination with resistance training and improvement in muscle strength" (Question EFSA No Q-2015-00437) 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 opinion on 23 February 2016.

More specifically, the application subject to this working document related to the effects of: "Creatine in combination with resistance training and improvement in muscle strength".

The Commission presented the working document and the health claim therein. No comments were raised by the delegations. The matter will be referred for further discussion at experts' level.

A.04 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 "Fabanol® Max, a standardised aqueous extract from *Phaseolus vulgaris* L., and reduction of the absorption of carbohydrates" (Question EFSA

No Q-2015-00123) pursuant to Regulation (EC) No 1924/2006 (Art. 13(5) of Regulation (EC) No 1924/2006) (Regulatory procedure with scrutiny).

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 opinion on 23 February 2016.

More specifically, the application subject to this working document related to the effects of: "Fabenol[®] Max, a standardised aqueous extract from *Phaseolus vulgaris* L., and the reduction of the absorption of carbohydrates".

The Commission presented the working document and the health claim therein. No comments were raised by the delegations. The matter will be referred for further discussion 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 (EFSA opinions Q-2014-00097, Q-2014-00058).

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 two 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.

More specifically, the applications subject to this draft measure relate to the effects of:

- Lactobacillus plantarum TENSIA[®] in the semi-hard Edam-type 'heart cheese' of Harmony[™] and maintenance of normal blood pressure;
- Carbohydrate solutions and maintenance of physical performance during endurance exercise.

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 on the draft Regulation. However, one delegation highlighted the need to provide as much guidance as possible to applicants, especially with respect to the risk assessments carried out for claims in order to reduce the number of unfavourable opinions received from EFSA. The Commission reminded that EFSA has produced extensive guidance for applicants for the authorisation of health claims, on the general evaluation of health claims as well as on specific health functions. The Commission also informed delegations that EFSA is currently in the process of updating its existing guidance documents.

Vote taken: Favourable opinion.

B.02 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 (EFSA opinions Q-2014-00580, Q-2014-00673, Q-2014-00566, Q-2014-00405, Q-2014-00624, Q-2014-00567).

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 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.

More specifically, the applications subject to this draft measure relate to the effects of:

- Caffeine and increased alertness for intakes of caffeine between 40 mg per serving and 75 mg per serving;
- an equimolar mixture (marketed under the trade names Clarinol[®] and Tonalin[®]) of the two conjugated linoleic acid (CLA) isomers c9,t11 and t10,c12, and contribution to a reduction in body fat mass;
- SYN BIO[®], a combination of *Lactobacillus rhamnosus* IMC 501[®] and *Lactobacillus paracasei* IMC 502[®], and maintenance of normal defecation;
- FRUIT UP[®], a carbohydrate extract from carob pods (*Ceratonia siliqua* L.), and a reduction of post-prandial blood glucose responses;
- a combination of pomegranate pomace extract (standardised by its content of punicalagins) and greater galangal rhizome powder (standardised by its content of acetoxychavicol acetate) and an increase in the number of motile spermatozoa in semen;
- *Bifidobacterium bifidum* CNCM I-3426 and defence against pathogens in the upper respiratory tract;
- Coffee C21, a coffee standardised by its content of caffeoylquinic acids, trigonelline and N-methylpyridinium, and reduction of DNA damage by decreasing spontaneous DNA strand breaks.

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 in the substance of the draft measure. One delegation made an editorial suggestion which was considered to improve the text and was taken into account.

Vote taken: Favourable opinion.

B.03 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 (EFSA opinion Q-2014-00366).

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 the use of 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. More specifically, the application subject to this draft measure relates to the effects of Symbiosal[®], a mixture of sea salt (97%) with chitosan (3%), and lowering of blood pressure. Increased blood pressure is a risk factor for hypertension.

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.

B.04 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 children's development and health (EFSA opinion Q-2014-00404).

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 the use of one health claim made on foods and referring to children's development and health, pursuant to Article 14(1)(b) of Regulation (EC) No 1924/2006. More specifically, the application subject to this draft measure relate to the effects of the consumption of β -galactosidase from *Kluyveromyces lactis* in Colief[®] and a reduction of gastrointestinal discomfort.

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.

B.05 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 children's development and health (EFSA opinion Q-2014-00462).

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 the use of one health claim made on foods and referring to children's development and health, pursuant to Article 14(1)(b) of Regulation (EC) No 1924/2006. More specifically, the application subject to this draft measure relate to the effects of Equazen eye q[®], a combination of EPA, DHA and GLA (at a weight ratio of 9:3:1), and improving reading ability in children.

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.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Regulation authorising a health claim made on foods and referring to children's development and health (EFSA opinion Q-2014-00826).

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 authorising one health claim made on foods and referring to children's development and health, pursuant to Article 14(1)(b) of Regulation (EC) No 1924/2006. More specifically, the application subject to this draft measure relate to the effects of vitamin D and contribution to the normal function of the immune system in children.

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 and the health claim therein. There were no comments or observations by the delegations with respect to the content of the draft Regulation.

Following the request of one delegation, it was agreed that further discussion would take place at experts' level in view of reaching a common understanding on the scope of this type of health claims.

Vote taken: Favourable opinion.

B.07 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 (EFSA Journal 2011;9(4):2053 and 2011;9(4):2054).

The draft Commission Regulation aims at amending Regulation (EU) No 432/2012 establishing the list of permitted Article 13(1) health claims by including four new health claims in the Annex of permitted health claims. In particular, this draft concerned:

- Two claims targeting adults performing endurance exercise:
 - Caffeine contributes to an increase in endurance performance
 - Caffeine contributes to an increase in endurance capacity
- Two claims targeting the general adult population:
 - Caffeine helps to increase alertness

- Caffeine helps to improve concentration

The draft Regulation was presented to the Committee for an exchange of views and possible adoption. It was recalled to the Committee that the health claims on caffeine were put on hold since 2012 pending further scientific assessment by EFSA. EFSA's scientific opinion [1] on the caffeine intake from all sources was published in May 2015. The Commission highlighted the need to continue with the progressive adoption of the list of permitted health claims as required by Regulation (EC) No 1924/2006 in its Article 13(3) as quickly as possible.

Some delegations expressed concerns as regards the draft Regulation. More specifically, one delegation opposed to the draft Regulation considering that it does not provide sufficient consumer protection and pointed out the need for additional warnings to be included in the conditions and restrictions of use of the claim. Another delegation did not oppose to the claims concerning the general population, however, it objected to the claims concerning people performing endurance exercise considering that the conditions of use raised safety concerns. Lastly, a third delegation refrained from supporting the authorisation of such claims arguing that consumption of caffeine should not be encouraged and that children can easily access caffeine-containing products that do not bear sufficient information on their labelling.

The rest of the Member States expressed support for the draft, nevertheless they insisted on some modifications in the draft Regulation which would shed further clarification as regards the restriction of use of these claims and the concerned target groups. More specifically, a majority of Member States sought clarification that the restriction to use this claim on foods addressed to children would also include adolescents and that the claims on endurance exercise and capacity would indeed only be used on foods targeting exclusively adults performing endurance exercise. The view that there is a need to specifically refer to adolescents was not shared by one delegation.

The Commission also clarified to the Committee that the fifth claim on caffeine that was on hold, i.e. caffeine contributes to a reduction in the rated perceived exertion/effort during exercise, would be rejected by virtue of the authorisation of this draft Regulation and that the rationale for this rejection was that the safety assessment of EFSA did not support the authorisation of that claim.

In the light of the comments received, very focussed changes to the text were made to further clarify some of the issues raised and the Committee proceeded with the vote.

[1]

http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/4102.pdf

Vote taken: Favourable opinion.

B.08 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 (EFSA Journal 2010;8(2):1466 and 2015;13(11):4287).

The Commission presented the draft Regulation amending the list of Regulation (EU) No 432/2012 concerning two authorised health claims made on meal replacement for weight control.

The amendments were proposed in order to ensure, that after the repeal of Directive 96/8/EC the already authorised two health claims related to meal replacement for weight control can be continued to be used according to the favourable opinion given by EFSA in 2010. Additional amendments regarding the vitamin and mineral contents of meal replacement for weight control were proposed in line with EFSA statement on the conditions of use for health claims related to meal replacement for weight control. On the question of one Member State the Commission explained that the addition of vitamin K will become mandatory after the three years of transition period provided by the draft Regulation. One Member State stated that the information 'meal replacement for weight control' should only be given on a product if the product uses the relevant authorised claim. There were no other comments or observations by the delegations.

Vote taken: Favourable opinion.

C.01 Exchange of views of the Committee on a draft Commission Regulation authorising certain health claims 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 the authorisation of two health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health, namely on the:

- Consumption of foods/drinks containing <name of all used non-fermentable carbohydrates> instead of fermentable carbohydrates contributes to the maintenance of tooth mineralisation.
- Consumption of foods/drinks containing <name of all used non-digestible carbohydrates> instead of sugars induces a lower blood glucose rise after their consumption compared to sugar-containing foods/drinks.

The health claims submitted pursuant to Article 13(5) obtained a favourable assessment by the European Food Safety Authority (EFSA) and accordingly they should be authorised. The Commission presented the draft Regulation and no comments or observations were raised by the delegations on this draft measure.

Taking into consideration the discussions at experts' level, it was reminded to the Committee that the EFSA Scientific Opinion on Dietary Reference Values for carbohydrates and dietary fibre [1] provides good reference for the carbohydrates which are identified as non-digestible carbohydrates.

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

[1]

http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/1462.pdf

C.02 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.

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. More specifically, the application subject to this draft measure relates to the effects of fibre sourdough rye bread and reduction of post-prandial glycaemic responses. The claim was submitted pursuant to Article 13(5) and received a favourable assessment by the European Food Safety Authority (EFSA).

The Commission presented the draft Regulation and recalled the reservations as regards the authorisation of this claim. Despite EFSA's positive scientific assessment, this health claim was considered as not complying with the requirements of Regulation (EC) 1924/2006. In particular, it was considered that such a health claim would suggest that high-fibre sourdough rye bread has particular characteristics in relation to the reduction of post-prandial glycaemic responses when compared with glucose, while in fact almost all foods have that effect, and was thus regarded as misleading.

No comments or observations were raised by the delegations and there was consensus on the draft Commission Regulation. One delegation, although supported the draft Regulation and the decision taken therein, it wished to make the remark that the outcome of the risk assessment was not on the same health claim as the one that the applicant originally submitted for authorisation.

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

M.01 Low level DNP in food supplements

The UK delegation presented its concerns to the Committee on the use of the substance 2,4-Dinitrophenol (DNP) in slimming pills and so-called "fat burners". The UK asked the views of the Commission and of the other Member States on whether it would be considered reasonable to start the procedure under Article 8 of Regulation (EC) No 1925/2006. The Commission reminded the Committee that in order for the procedure under Article 8 to be initiated, the request must fulfil certain conditions as laid down by Commission Implementing Regulation (EU) No 307/2012, such as that the food product containing the concerned substance is placed on the market in one or more Member States. The majority of Member States present were in favour of a

request to initiate the procedure under Article 8 for this substance. The Commission invited the UK delegation to submit the request and the available information to the Commission in order for it to be examined in the light of the afore-mentioned conditions.

M.02 Exchange of views on the First Report of the Scientific Committee for Food concerning the essential requirements of weaning food

In preparation of the forthcoming request of the Commission to EFSA to carry comprehensive update on the composition requirements on processed cereal-based food and baby food, the Commission invited Member States to comment on the approach of the First Report of the Scientific Committee for Food concerning the essential requirements of weaning food. This Report served as scientific basis when composition requirements of processed cereal-based food and baby food were laid down in Directive 2006/125/EC. A group of Member States supported the approach of the First Report of the Scientific Committee and referred to relevant products present on the market. Member States were invited to send comments also in writing.