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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 07 DECEMBER 2018

(Section *General Food Law*)

CIRCABC Link: *https://circabc.europa.eu/w/browse/2962037c-8837-41db-9be8-4deb316fb4cb*

A.01 Exchange of views of the Committee on a notification by Latvia (2018/0421/LV) of a draft Regulation regarding plants, parts of plants and other substances prohibited or restricted for use in foods.

On 27 August 2018, the Latvian authorities notified under the procedure laid down in Article 12 of Regulation (EC) No 1925/2006 (addition of vitamins and minerals and of certain other substances to foods) a draft Regulation that establishes lists of plants, parts of plants and other substances prohibited or restricted for use in foods, and that lays down the procedure for the notification of the distribution, registration and withdrawal of the registration of compound foods containing plants. Latvia presented the notified text and explained that the Annexes I and II to the draft measure list those plants or parts of plants that may not be used in food because they are considered to be harmful to health due to the presence of toxic substances, or the use of which is restricted in food due to the presence of chemically active substances, and the safety of which shall be assessed by the Latvian authorities in accordance with a notification procedure laid down in the notified draft measure. Latvia further explained that the Annex III to the draft measure lays down a list of certain substances other than vitamins and minerals for which a maximum daily intake is specified.

During the exchange of views, a Member State requested clarifications on the maximum daily intake set out for the substances N-acetylcysteine and glucosamine. Two Member States expressed their concerns with regard to the setting of a maximum daily intake for monacolins obtained from red yeast rice as discussions on a risk management decision under Article 8 of Regulation (EC) No 1925/2006 are currently ongoing. Another Member State requested a clarification as to whether the list of botanicals in the BELFRIT (Belgium, France and Italy) project had been taken into consideration. Latvia confirmed that the BELFRIT list was used as a basis for the establishment of the lists in the Annexes to the notified draft measure.

Three Member States took the opportunity to express their support for further harmonisation in the area of botanicals.

The Commission took note of the comments for further harmonisation of the use of botanicals and explained that the conclusions from the ongoing REFIT evaluation of the health claims legislation that is also assessing the general regulatory framework for the use of botanicals, will be important with respect to any future action in terms of harmonisation in this area. In this respect, the Commission explained that a Staff Working Document is envisaged to be published by June 2019 and will lead to further discussions on the matter.

The Commission shall issue its opinion under the procedure of Article 12 of Regulation (EC) No 1925/2006 within the standstill period of 6 months.

A.02 Exchange of views of the Committee on a notification by Finland on the country of origin labelling of meat used as an ingredient of foods delivered by mass caterers.

On 11 October 2018, the Finnish authorities notified a measure requiring the indication of the country of origin of meat used as an ingredient and offered for the final consumer by mass caterer. The standstill period expires on 12 January 2019.

The Finnish authorities presented their notified measure explaining that the draft measure requires the indication of the country of origin/place of provenance of the fresh, chilled and frozen meat used as food ingredient of beef, swine meat, sheep and goat meat, poultry meat. The notified draft applies to non-prepacked meat offered by mass caterers, has experimental character, has a validity limited to 2 years and foresees reporting on the application to the Commission before the end of the validity period (4 months before the end of its application).

The Finnish authorities provided the reason for justifying the draft measure and explained that the majority of consumers attach significant value to the information in question. The Finnish authorities also stated that they would favor harmonised measures at EU level for country of origin indication of food. However, in the absence of such measures, introducing provisions at national level remains the ultimate solution for Finland.

Some Member States stated their preference to harmonise at EU level the country of origin indication for all foods. One Member State stated that the requirements to introduce a national measure on additional mandatory indication of the country of origin, as laid down in Article 39 of Regulation (EU) No 1169/2011, is not fulfilled in relation to the Finnish draft measure, as the link between the origin and the quality of the food is not proven. Another Member State referred to the ongoing preliminary ruling of the Court of Justice on the matter.

The Commission took note of the observations expressed and informed that the assessment of the notified draft is ongoing

A.03 Exchange of views of the Committee on a notification by Poland (2018/537/PL) of a draft Regulation amending the Regulation on labelling potato tubers other than seed potatoes.

The Polish authorities notified on 14 November 2018 a measure requiring the country of origin indication of potatoes. The standstill period expires on 15 February 2019.

The Polish authorities presented the draft measure while explaining that the notified draft requires the indication of the origin of prepacked and non-prepacked potatoes.

As regards the justification of the draft measure the Polish authorities explained that the objective is to align requirements concerning the identification and labelling of the country of origin of potatoes with the requirement to indicate the country of origin of fresh fruits and vegetables covered by specific marketing standards by the EU. Potatoes are currently not covered by specific legislation requiring the origin indication of such products while there is high consumer interest in this kind of information. It was further explained, that according to the national research institute, Poland possesses a number of specific scientifically proven conditions impacting on the quality characteristics of potato tubers, which makes potatoes production in Poland distinguishable from potatoes produced in other EU countries.

On the question of one Member State, the Polish authorities explained that the purpose of the draft measure is, rather than to promote Polish products, to give information in general about the origin of potatoes.

One Member State stated that the indication of the country of origin should be put in place to address traceability related concerns.

The Commission took note of the observations expressed and informed that the evaluation of the notified draft is ongoing.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards trans fat, other than trans fat naturally occurring in animal fat, in foods intended for the final consumer.

This draft Regulation was submitted to the Standing Committee in accordance with Article 8 of Regulation (EC) No 1925/2006. It aims at establishing a legal limit for the content of industrial trans fat in foods of 2g per 100g of fat. Following the feedback mechanism the draft accommodates the concerns of the catering sector and SMEs with regard to the scope to cover not only foods destined to final consumers but also for supply to retailers and to introduce an obligation for business to business transmission of information on the amount of trans fat when it exceeds 2% of total fat.

Member States were very satisfied with the proposed extension of the scope of the measure to include food intended for supply to retail. Final adjustments were made during the meeting to clarify the legal definition of retail and ensure consistency between the articles and the Annex.

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 children's development and health.

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) of Regulation (EC) No 1924/2006. More specifically, the application subject to this draft measure relates to the effects of "'Nutrimune®' supports the immune defence in the gastrointestinal and upper respiratory tract of young children". 'Nutrimune®' is a pasteurised (a pasteurised cow's skim milk fermented with Lactobacillus paracasei CBA L74.

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 in the substance of the draft measure.

Vote taken: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards Yohimbe (Pausinystalia yohimbe (K.Schum) Pierre ex Beille).

The Commission explained that this draft Commission Regulation aims at prohibiting the use of Yohimbe in food by placing the substance in Part A of Annex III of Regulation (EC) No 1925/2006.

The Commission recalled that in 2013 the European Food Safety Authority (EFSA) adopted a scientific opinion on the evaluation of the safety in use of Yohimbe and concluded that it was not possible to provide advice on a daily intake of Yohimbe bark and its preparations that does not give rise to concerns for human health. As there was a possibility of harmful effects on health associated with the use of Yohimbe and its preparations in foods, but scientific uncertainty persisted, pursuant to the procedure laid down in Article 8 (2) of Regulation (EC) No 1925/2006 the substance concerned was put under community scrutiny by mean of Commission Regulation (EU) No 2015/403.

Pursuant to Article 8(5) of Regulation (EC) No 1925/2006, within four years from the date a substance has been listed in Part C of Annex III, a decision shall be taken to generally allow the use of a substance listed in Part C of Annex III or to list it in Part A or B of Annex III, as appropriate, taking into account the opinion of EFSA on any files submitted for evaluation by food business operators, or any other interested parties. Considering that interested parties have not submitted any scientific data to EFSA to demonstrate the safety of Yohimbe within the time limit referred to in Article 5(2) of Implementing Regulation (EU) No 307/2012, it is appropriate to prohibit the use of the substance in food by placing it in Part A of Annex III to Regulation (EC) No 1925/2006.

Vote taken: Favourable opinion.

C.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation authorising a health claim made on foods and referring to the reduction of disease risk.

This draft Commission Regulation was presented to the Standing Committee in accordance with Article 17(1) of Regulation (EC) No 1924/2006 on nutrition and health claims made on foods. This draft aims at the authorisation of one health claim made on foods and referring to the reduction of disease risk in accordance with Article 17(3) of Regulation (EC) No 1924/2006. The concerned health claim is the following: "*A combination of artichoke leaf dry extract standardised in caffeoylquinic acids, monacolin K in red yeast rice, sugar-cane derived policosanols, OPC from French maritime pine bark, garlic dry extract standardised in allicin, d-α-tocopheryl hydrogen succinate, riboflavin and inositol hexanicotinate reduces blood LDL-cholesterol concentrations. High LDL-cholesterol is a risk factor in the development of coronary heart disease.*"

The Commission summarised the discussions held in the past with the Member States about the safety concerns on Monacolin K. The Commission further reminded the delegations that the procedure of Article 8 of Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods was launched to address those safety concerns in a holistic manner, for which a final decision has not been adopted yet.

Many delegations took the floor and expressed their position on the authorisation of this claim. One delegation insisted that the Article 8 procedure and the authorisation of the claim are two distinct procedures and that one process should not hinder the other one. This delegation also added that the health claim in question concerns a daily intake of 2 mg of monacolin K that is below the daily limit that EFSA, in its scientific opinion, suggests to give rise to safety concerns[1].

The remaining delegations that expressed their views (nine delegations) strongly supported that the claim's authorisation procedure should wait for the final decision under the Article 8 procedure. Delegations further argued that the EFSA opinion on the safety of monacolin K in foods highlights many grey areas about the safety of monacolin K. Therefore, consumers should not be further exposed to claims on this substance before its safe use in foods has been ensured.

While the Commission recognised its legal obligation to act for both procedures, it also acknowledged the concerns raised by the delegations to proceed at this stage with the authorisation of a claim on such a substance. Against this background, it was decided to suspend the health claim authorisation procedure and resume it once the Article 8 procedure of Regulation (EC) No 1925/2006 has been completed.

M.01 French decree

One Member State asked when the evaluation report on the French decree requiring the indication of the country of origin of milk, milk and meat used as ingredient is going to be sent to the Commission. In their reply, the French authorities explained that the report is on its way and can be expected soon.

[1] EFSA ANS Panel (EFSA Panel Food Additives and Nutrient Sources added to Food), Younes M, Aggett P, Aguilar F, Crebelli R, Dusemund B, Filipic M, Frutos MJ, Galtier P, Gott D, Gundert-Remy U, Kuhnle GG, Lambré C, Leblanc J-C, Lillegaard IT, Moldeus P, Mortensen A, Oskarsson A, Stankovic I, Waalkens-Berendsen I, Woutersen RA, Andrade RJ, Fortes C, Mosesso P, Restani P, Pizzo F, Smeraldi C and Wright M, 2018. Scientific opinion on the safety of monacolins in red yeast rice. EFSA Journal 2018;16(8):5368, 46 pp. https://doi.org/10.2903/j.efsa.2018.5368