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Health and Food Safety Directorate General

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Standing Committee on Plants, Animals, Food and Feed

Section *General Food Law*

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SUMMARY REPORT

A.01 Exchange of views of the Committee on a Belgian notification of a draft Royal Decree amending the Royal Decree of 31 August 2021 on the manufacture and marketing of foodstuffs composed of or containing plant preparations (2022/0532/B).

On 27 July 2022, the Belgian authorities notified a draft Royal Decree amending the Royal Decree of 31 August 2021 on the manufacture and marketing of foodstuffs composed of or containing plant preparations. The notification was made under Article 45 of Regulation (EU) No 1169/2011 on food information to consumers as well as under Article 12 of Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain substances to foods. Belgium presented the notified measure as well as the reasons justifying it. During the subsequent discussion, two Member States expressed concerns about the deletion of certain plants and plant parts from the Belgian list of plants that are allowed in the manufacture of food supplements. Belgium clarified that those plants have been removed from the list in the absence of history of their safe use in food.

The Commission took note of the comments made and informed that the assessment of the notified draft is ongoing.

A.02 Supply issues in the EU food sector due to Russia's invasion of Ukraine and related labelling challenges: exchanges of information with Member States.

One Member State explained that the vegetable oil trade situation is not stabilised, that its national labelling transitional measures put in place in this context have been extended until April 2023 and called for EU actions, such as:

- the setting up of a list on the Commission website of national labelling-related measures or alternatively a reference to the national websites where these measures can be found.
- an agreement between Member States on the scope and timing of national provisional measures.

- the inclusion in the FIC Regulation of provisions providing for the possibility for the Commission to decide on provisional measures in case of exceptional circumstances.

Upon a question from this Member State, it was confirmed during the meeting that all Member States accept the use of stickers on food labels when justified as a provisional measure for FBOs to provide the relevant information to consumers.

Two other Member States expressed their support for an EU harmonised approach.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annex II to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards nicotinamide riboside chloride added to foods.

The draft Commission Regulation aiming at including the substance nicotinamide riboside chloride in Annex II to Regulation (EC) No 1925/2006 and thereby to permit its addition to foods was presented to the Committee. The substance has received a favourable scientific assessment by the European Food Safety Authority and is included in the Union list of novel foods laid down in Commission Implementing Regulation (EU) 2017/2470. During the exchange of views, five Member States noted that a footnote making reference to the novel food authorisation of the substance should be provided for by the draft measure and inserted in Annex II to Regulation (EC) No 1925/2006 to enable food business operators and control authorities to make the connection between the two legal frameworks.

The Commission explained that this comment will be considered in the context of future inclusions.

Outcome of the vote by written consultation: 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 than those referring to the reduction of disease risk and to children's development and health.

The draft Commission Regulation aiming at the refusal of authorisation of four health claims to be made on foods related to Beta-glucans, Affron®, MegaNatural® and Fructalose®, was presented to the Committee. There were no comments on the draft.

Outcome of the vote by written consultation: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) refusing to authorise a health claim made on foods and referring to children's development and health.

The draft Commission Regulation aiming at the refusal of authorisation of a health claim to be made on foods related to organic foods, was presented to the Committee.

One Member State noted that they have linguistic comments for the French version of the draft, which they will send in writing after the meeting. There were no other comments on the draft.

Outcome of the vote by written consultation: Favourable opinion.

M.01 Request from Belgium – on the interpretation of the judgment of the CJEU in case C 533/20 regarding the designation of vitamins in the list of ingredients, and in particular its scope.

The Commission explained that the Court held that where a vitamin has been added to a food, the list of ingredients of that food does not have to include, in addition to the general name of the vitamin, the specific name of the vitamin formulation.

The Court's judgment does not preclude that the vitamin formulation is also indicated, on a voluntary basis, in the list of ingredients of fortified foods, in addition to the general name of the vitamin, as long as the conditions of Article 36 of Regulation (EU) No 1169/2011 on food information to consumers are complied with. In other words, the voluntary indication of the vitamin formulation in the list of ingredients of fortified foods is not prohibited on the basis of the judgment alone.

With regard to the scope of the case, the Commission noted that it concerned the indication of vitamins in the list of ingredients of fortified foods.

The Court held that the wording of Articles 18(2) and 17(1) of Regulation (EU) No 1169/2011 cannot determine on its own the name under which a vitamin that has been added to a food must be designated in the list of ingredients of that food (see paragraphs 35-36 of the judgment). Therefore, in its interpretation of the provisions of Regulation (EU) No 1169/2011, the Court took into account, amongst others, the context and the objectives of Regulation (EC) No 1925/2006 on food fortification (see paragraphs 38-43). Consequently, the judgment does not relate to the indication of vitamins in the list of ingredients of all foods, including food supplements.

In view of that, the implications of the Court's ruling for the indication of vitamins in the list of ingredients of food supplements have to be further assessed, as that legal framework is considerably different with regard to its objectives, specific labelling provisions, nutrition declaration, the profile of the average consumer etc. In this regard it is necessary to bear in mind the following:

Firstly, the Court noted in paragraph 42 of its judgement that the purpose of Regulation (EC) No 1925/2006 is not the provision of information to consumers relating to the presence of vitamins in those foods, as nutrition labelling of fortified foods is exclusively regulated by Regulation (EU) No 1169/2011. In contrast thereto, nutrition labelling of food supplements is regulated by Directive 2002/46/EC on food supplements. The purpose of the Directive 2002/46/EC, as reflected in recital 18, is the provision of information on the nutrients of food supplements, in order to allow consumers to make an informed choice and use them properly and safely. As stated in recital 18, Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling for foodstuffs (which has been repealed and replaced by Regulation (EU) No 1169/2011) did not apply to food supplements, as in view of the nature of food supplements, nutrition labelling should be confined to the nutrients actually present and be compulsory. Articles 6, 8 and 9 of Directive 2002/46/EC regulate the mandatory particulars to be indicated on food supplements and the declaration of the amount of nutrients present in the product. Therefore, the Court's reasoning in paragraphs 43 and 44 of the judgment cannot apply by analogy with regard to the indication of vitamins on food supplements.

Secondly, the Court considers in paragraphs 45 to 49 that the designation of vitamins in a coherent and exclusive manner under names such as 'Vitamin A' in the nutrition declaration and in the list of ingredients is capable of ensuring that the information

provided is accurate, clear and easy to understand for the average consumer, who is reasonably well informed and reasonably observant and circumspect. In contrast thereto, first, food supplements do not bear a nutrition declaration and, secondly, it could be argued that the average consumer of fortified foods and the average consumer of food supplements differ. As the Advocate General notes in paragraph 79-80 of her Opinion, the information needs of consumers of fortified foods and of food supplements may differ. Therefore, the Court's reasoning in paragraphs 45 and 49 of the judgment cannot apply by analogy with regard to the indication of vitamins on food supplements.

Thirdly, while Annex II to Regulation (EC) No 1925/2006 makes reference to 'vitamin formulations' that may be used in the manufacture of foods, Annex II to Directive 2002/46/EC refers to 'Vitamin and mineral substances which may be used in the manufacture of food supplements'. Thus, the argumentation of the Court in paragraph 42 of its judgment that "The vitamin formulations listed in Annex II to Regulation (EC) No 1925/2006 cannot therefore be regarded as names that are additional to those referred to in paragraph 39 above, especially since the annex states that they are only 'forms' of each of the vitamins concerned" does not apply by analogy with regard to food supplements.

As the Advocate General notes in point 66 of her Opinion, "*the interpretation of Article 18(2) of Regulation (EU) No 1169/2011 may have different outcomes depending on the particular food at issue, without affecting, in my view, the consistent application of that provision in the context of EU food information law*".

Finally, the Commission representative noted that the ultimate responsibility for the interpretation of EU law lies with the Court of Justice.

M.02 Request from Greece – on the Irish measure on alcohol labelling.

The Commission presented the state of play of the Irish measure on alcohol labelling. It was reminded that in June 2022, the Irish authorities notified under Regulation (EU) No 1169/2011 on food information to consumers (FIC Regulation) and under Directive (EU) 2015/1535 on the provision of information in the field of technical regulations, draft measures implementing Article 12 of the Public Health (Alcohol) Act 2018 (hereinafter basic Act) providing labelling obligations of alcoholic beverages.

It was explained that the 2018 basic Act was notified in 2016 (notification 2016/42/IE) and complementary provisions in 2018 (notification 2018/22/IE) to which the Commission had provided comments. The basic Act adopted and published by the Irish authorities in 2018 provides for implementing measures to be adopted, which are the measures notified in June 2022.

The elements of the respective draft measures notified in June 2022 were assessed under Article 39 of the FIC Regulation with regard to the wordings of the health warnings and under the TRIS procedure with regard to the presentation of the energy value and the alcohol content.

The Commission informed the Committee that the procedure under the FIC Regulation was closed on 22 September 2022 (3 months after the notification of the draft by the Irish authorities). It should be noted that for what concerns the TRIS procedure, the deadline has been extended until 22 December 2022 following the detailed opinions of certain Member States.