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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***

**05 October 2021**

***CIRCABC Link:*** *https://circabc.europa.eu/w/browse/32c4696c-fb96-4ada-bce6-e86f716a40b4*

# SUMMARY REPORT

## A.01 Update on the legislative proposal establishing a framework for a Union Sustainable Food System, including on sustainability labelling.

The new legislative proposal establishing a framework for a sustainable food system was presented to Member States. No comments/questions from Member States.

## A.02 Information point on import-export issues between the EU and UK(GB).

In view of the end of the transition period provided in the EU-UK Withdrawal Agreement on 31 December 2020 and as part of the Commission's actions to ensure readiness following the UK withdrawal from the Internal Market and the EU Customs Union (among others) at the exception of Northern Ireland that remain aligned to certain provisions of EU law, the Commission invited Member States to pose questions relating to actions needed to implement the Withdrawal Agreement in the field of food information to consumers, nutrition and health claims, food for specific groups, food supplements, food fortification and natural mineral waters. The Commission received questions from Ireland and France and provided the replies below:

**Ireland asked the following questions:**

*Could the Commission advise if a compound food (for example a pre-packaged sandwich or lasagne) is made with an ingredient that is fortified to a significant amount, such as flour or spreadable fat, must the final food (the sandwich or lasagne) be fortified to a significant amount before being placed on the market because it includes a fortified ingredient?*

*Could the Commission advise, if a compound food (for example frozen pizza) is made from an ingredient fortified under a Member State national derogation listed on the community register as laid down by Article 9, for example made using iodised salt from Italy, must the final food (frozen pizza) be fortified to a significant amount (in this example with additional iodine) because it includes a fortified ingredient?*

**France asked the following question:**

*The United Kingdom benefited from a derogation under Article 11 of Regulation (EC) No 1925/2006 allowing it to enrich flour. This flour was included in the manufacture of biscuits, for example, which could then circulate freely on the territory of the Union.*

*Should we accept the placing on the market of these biscuits, or refuse it on the grounds that they do not meet the conditions provided for by Regulation (EC) No 1925/2006, according to which a product can be enriched with vitamins / minerals only under condition to lead to the presence of a significant quantity of this vitamin / mineral in the finished product (in practice 15% of the NRVs)?*

*This question refers to the more general question of knowing whether an enriched ingredient complying with Regulation (EC) No 1925/2006 can be used in the manufacture of a compound foodstuff which does not reach 15% of the NRVs for the vitamin / mineral supplied by the enriched ingredient. This is not possible from our point of view, but we are interested in the opinion of the Commission and other Member States.*

**The Commission provided the reply below:**

Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and certain other substances to foods, does not make any reference to ingredients. Likewise, Annex XIII Part A (2) to Regulation (EU) No 1169/2011 on food information to consumers sets significant amounts with regard to foods (products other than beverages, beverages, portions of foods), rather than food ingredients.

The purpose served by Regulation (EC) No 1925/2006, as expressed in Article 1 thereof, is to ensure the effective functioning of the internal market, whilst providing a high level of consumer protection. Foods containing lesser than significant amounts of vitamins and minerals constitute part of the normal diet of consumers, and therefore, the use of a fortified ingredient in a food that does not contain significant amounts of the fortified substance does not pose any health risks to consumers.

Based on the above, the Commission considers that if a compound food is made with an ingredient that is fortified to a significant amount, the final food is not required to be fortified to a significant amount to be placed legally on the Union market.

The Commission reminded Member States that the nutrition declaration of foods using fortified ingredients may include only vitamins and minerals present in significant amounts in the final food according to Article 30(2)(f) of Regulation (EU) No 1169/2011. Therefore, the labelling of a food containing a fortified ingredient has to comply with the provisions of Regulation (EU) No 1169/2011 and in particular it shall not be misleading for the consumers.

As regards flour imported from Great Britain, the Commission noted that it is considered as non compliant with the provisions of Regulation (EC) No 1925/2006, if it does not comply with the significant amounts. Bakery goods, though, containing the fortified flour are not infringing the provisions of the Regulation, as long as their labelling is not misleading. In particular, they cannot be market as fortified, or as containing fortified flour.

**Notice of withdrawal of recognition for natural minerals waters – England and Wales**

The Commission informed the Member States about the receipt of two letters from the United Kingdom, Department for environment, food and rural affairs and by the Welsh government and the Ministry of mental health and wellbeing, informing that Directive 2009/54/EC on the exploitation and marketing of natural mineral waters no longer applies to the United Kingdom, with the exception of the United Kingdom in respect of Northern Ireland.

The two letters serve as notice of cessation of accreditation of the established EU recognised natural mineral waters in England and Wales from January 7th 2022, in accordance with national legislations.

Member States were informed that all natural mineral waters which obtained their recognition in or by an EU Member State will no longer be authorised for import into England and Wales as natural mineral waters, unless they are recognised as such by a responsible authority of the United Kingdom.

Those producers affected by these measures can already apply for recognition to sell natural mineral water in Great Britainand if they wish to do so, they must obtain the recognition by January 7th 2022.

There were no questions from the Member States to the Commission.

**B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision concerning a draft Decree by the Kingdom of the Netherlands on toddler drinks and toddler milk notified in accordance with Article 45 of Regulation (EU) No 1169/2011.**

**B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision concerning a draft Decree by the Kingdom of the Netherlands on toddler drinks and toddler milk notified in accordance with Article 12 of Regulation (EC) No 1925/2006.**

Points B.01 and B.02 were discussed together, as they concerned the same notified national measures.

On 28 July 2020, the Dutch authorities notified to the Commission a draft Decree containing rules on foods based on (cow or goat milk) protein, to which at least one or more vitamins, minerals or other substances have been added, and which are intended to be used as a drink for young children between the ages of one and three years. The notified draft defines ‘toddler milks’ and ‘toddler drinks’ and lays down specific compositional, fortification, labelling and marketing requirements for such products.

The draft was notified in accordance with the notification procedure laid down in Directive (EU) 2015/1535, but also in accordance with Article 45(1) of Regulation (EU) No 1169/2011 on food information to consumers (FIC) and Article 12 of Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and certain other substances to foods (food fortification Regulation).

The Commission examined the notified draft and adopted under Directive (EU) 2015/1535 a detailed opinion on 26 October 2020, a negative opinion under FIC on 27 October 2020 and a negative opinion under the food fortification Regulation on 27 January 2021.

A Commission representative presented the two draft Implementing Decisions and explained that the Dutch authorities fail to provide any scientific justification that would substantiate the need to lay down specific compositional requirements with regard to "other substances" for the products marketed as 'toddler drinks' and 'toddler milk'. The Commission also explained that the additional labelling requirements set by the notified draft are misleading as to the nature of toddler drinks and toddler milk and therefore are in conflict with Article 7 (1)(a) of the Regulation (EU) No 1169/2011 and can not be justified on the grounds of consumer protection.

Following the presentation of the two draft Implementing Decisions nine Member States asked the Commission to launch a broader discussion on young child formulae at working group level. The Commission committed to organising a meeting at working group level to discuss the enforcement of the EU law provisions that apply to such products.

**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 monacolins from red yeast rice.**

Member States were informed about the outcome of the feedback consultation on this draft Commission Regulation. The consultation period ran until 17 June 2021, during which 29 feedbacks were submitted by different stakeholders. The majority of comments received raised concerns on:

- The proposed warning statement "should not be consumed by adults above 70 years old",
- The scope of the draft measure,
- The proposed maximum limit of less than 3mg/day for monacolins from red yeast rice,
- The lack of a transition period in the draft measure.

A Commission representative explained how those comments had been taken into account and presented the draft measure to Member States. During the exchange of views, the majority of Member States expressed their support for the draft measure, while asking for some clarification on:

- The novel food status of red yeast rice preparations in foods other than food supplements and whether it could be explained in a footnote in the measure,
- The possible revision of the authorised health claim on monacolins to bring it line with the restrictions of use for monacolins from read yeast rice proposed under Article 8 of Regulation (EC) No 1925/2006,
- The proposed maximum limit of less than 3mg/day for monacolins from red yeast rice, in particular, whether the limit could be amended to 3mg/day for practical reasons,
- The rational for the proposed labelling requirements in the measure questioning in particular the necessity of the proposed warning statements "*seek advice from a doctor on consumption of this product if you experience any health problems*"

and "*should not be consumed if you are taking cholesterol-lowering medication",*

- The availability of standardized analytical methods to quantify all individual monacolins in the final product.

On the specific questions raised by Member States, a Commission representative provided the following clarifications:

- Recital 6 of the draft measure intends to give an explanation about the novel food status of the substances concerned clarifying that the use of red yeast rice preparations in food categories other than food supplements is subject to an authorization under Regulation (EU) 2015/2283 on novel foods. It is legally not possible to include an additional footnote on this matter in Annex III of Regulation (EC) No 1925/2006.
- The health claim authorised by Commission Regulation (EU) 432/2012 that *"monacolin K from red yeast rice contributes to the maintenance of normal blood cholesterol levels"* may be used only for foods, which provide a daily intake of 10 mg of monacolin K from red yeast rice. As of the entry into force of the Commission Regulation amending Annex III to Regulation (EC) No 1925/2006, individual portions of products for daily consumption shall provide less than 3 mg of monacolins from red yeast rice. Consequently, foods that satisfy the conditions of use of the aforementioned health claim will not be able to be placed on the Union market. To provide legal certainty, within one year of the entry into force of the Regulation, the aforementioned authorised health claim will be removed from the Union list of permitted health claims by the procedure under Article 13(4) of Regulation (EC) 1924/2006 on nutrition and health claims made on foods. In the meantime, a footnote will be added in the EU Register of nutrition and health claims explaining that the health claim in question becomes obsolete in light of the amendment of Annex III to Regulation (EC) 1925/2006.
- The European Food Safety Authority (EFSA), in its scientific opinion considered that individual cases of severe adverse reactions have been reported for monacolins from red yeast rice at intake levels as low as 3 mg/day. In other words, severe adverse reactions have occurred already at an intake level of 3mg/day. Based on these conclusions allowing the marketing of food containing monacolins at 3 mg would not protect adequately consumers` health.
- The rationale for the proposed additional labelling requirements was to ensure the highest level of protection for consumers, especially for vulnerable subgroups of purchasing products containing monacolins from red yeast rice. EFSA in its scientific opinion noted that the profile of adverse effects to red yeast rice was similar to that of lovastatin hence, it was considered appropriate to warn persons to seek medical advice if they experience any health problems. Furthermore, as EFSA identified a risk of adverse effects due to interactions with medicinal products, it was considered necessary to warn persons using cholesterol-lowering medicines to avoid concomitant use of foods and food supplements containing monacolins from red yeast rice.

- As to the possible presence of monacolins other than monacolin K in red yeast rice, EFSA in its scientific opinion noted that on the basis of the information available in the literature, different monacolins have been identified in red yeast rice samples. These molecules include monacolin J (lovastatin diol lacton), monacolin L (the precursor of monacolin J), dehydromonacolin K (dehydrolovastatin), compactin (mevastatin). Practical methods that quantify all monacolins in red yeast rice preparations could not be identified. In the absence of these methods monacolin K, the most abundant monacolin found in red yeast rice, is typically used as a marker to quantify the monacolin-content in red yeast rice preparations. In red yeast rice, monacolin K exists in lacton and hydroxyacidic forms in equilibrium. Therefore, the sum of the analysed contents of monacolin K (lacton) and monacolin K (hydroxy acid) can be used to quantify the total monacolin content in preparations from red yeast rice.

Some Member States asked for the inclusion of a transitional period in the measure to ensure legal certainty and clarity concerning those non-compliant products that have been lawfully placed on the EU market before the entry into force of the regulation.

It was explained that due to the severe harmful effects monacolins may have on health, the inclusion of a transition period in the measure would not be appropriate. Concerning products legally placed on the market before the entry into force of the measure, the Commission provided the following clarification:

*"As of the entry into force of the Commission Regulation amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards monacolins from red yeast rice, the addition to foods or the use in the manufacture of foods of monacolins from red yeast rice that do not comply with the restrictions set in Annex III, Part B of Regulation (EC) No 1925/2006 shall be prohibited. In parallel, the provisions of Regulation (EC) No 178/2002 apply.*

*Article 14(1) of Regulation (EC) No 178/2002 provides that food cannot be placed on the market if it is unsafe, meaning that it is injurious to health or unfit to human consumption.*

*According to Article 17(1) of Regulation (EC) No 178/2002 food business operators at all stages of production, processing and distribution within the businesses under their control shall ensure that foods satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met.*

*Following the entry into force of the Regulation, foods, including food supplements, that do not comply with the restrictions set in Part B of Annex III to Regulation (EC) No 1925/2006 cannot benefit from the presumption of safety laid down in Article 14(7) of Regulation (EC) No 178/2002.*

*For all these reasons, foods, including food supplements, that do not comply with the restrictions set in Part B of Annex III to Regulation (EC) No 1925/2006 shall not be made available on the Union market as of the day of entry into force of the Commission Regulation amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards monacolins from red yeast rice."*

**M.01 Update on state of play Farm to Fork Strategy: front of pack nutrition labelling, nutrient profiles, origin labelling, date marking, alcoholic beverages**

Belgium asked for an update the state of play Farm to Fork Strategy: front of pack nutrition labelling, nutrient profiles, origin labelling, date marking, alcoholic beverages. A Commission representative explained that the Europe's Beating Cancer Plan adopted on 3 February 2021 announced a Commission proposal to introduce the "mandatory indication of the list of ingredients and the nutrition declaration on alcoholic beverage labels". In that context, the Commission published in June, an inception impact assessment on alcoholic beverages labelling.

An overview of the feedbacks received was presented at the meeting (all contributions are available at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13028-Food-labelling-revision-of-rules-on-information-provided-to-consumers-for-alcoholic-beverages_en).

Upon question, it was clarified that the way forward regarding the announcement on health warnings is under discussion.

A general update was provided on the ongoing work for preparing a proposal for a revision of the Food Information to Consumers Regulation in the area of front-of-pack nutrition labelling / nutrient profiles, origin labelling, data marking and labelling of alcoholic beverages. The state of play of different ongoing studies (EFSA, JRC, consumer research study) was provided and also more information on the study supporting the impact assessment carried out by an external contractor. In the context of the latter study, several consultation activities are scheduled. Finally, an overview of the next steps was presented.

**M.02 Update on state of play Farm to Fork Strategy: reformulation**

Sweden asked for an update on the state of play of the reformulation initiative under the Farm to Fork Strategy. A Commission representative explained that the EU Code of Conduct on Responsible Food Business and Marketing Practices entered in force in July 2021. Reformulation commitments are among the commitments made within the frame of the Code and the Commission will be assessing progress within the assessment made under the Code. No other new initiatives on food reformulation are currently planned.

The Commission will also continue working with its partners on the Joint Action Best Remap.