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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 notification by the Netherlands (2020/482/NL) of 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 (Commodities Act Decree on toddler formula and toddler milk) notified to the Commission according to Article 12 of Regulation (EC) No 1925/2006 and to Article 45 of Regulation (EU) No 1169/2011.

On 28 July 2020, the Dutch authorities notified via TRIS and 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) and of Article 45 of Regulation (EU) No 1169/2011 (food information to consumers), a draft Decree on toddler drinks and toddler milk. The Netherlands presented the notified text and explained that the draft measure aims to remove restrictions laid down in national legislation on the addition of certain nutrients and substances to foods so as to make it possible for 'toddler drinks' and 'toddler milk' to be sold on the Dutch market. The Netherlands further explained that the draft measure does not lay down any requirements to add vitamins and minerals to these products and that the relevant horizontal EU food legislation applies as they are considered to be normal foods. Furthermore, the Netherlands clarified the reasons for the additional labelling requirements.

An exchange of views was held on the draft measure, in particular on the necessity of these products for young children in the light of the advice of the European Food Safety Authority that these products are not necessary for young children and that follow-on formula can continue to be used beyond the age of one year. Some delegations expressed their support for the approach taken by the Netherlands in this draft measure whereas other delegations did not agree with this approach as these products should be regulated as normal foods and therefore should comply with the relevant horizontal rules.

Some delegations expressed their views with regard to the deviation from the rules laid down in Article 6(6) of Regulation (EC) No 1925/2006 and of Regulation (EU) No 1169/2011 as regards reference nutrient intakes, as well as the potentially misleading nature of referring to rules laid down in Commission Delegated

Regulation (EU) 2016/127 on infant formula and follow-on formula. An exchange of views was also held on the designations 'toddler milk' and 'toddler drinks' and on the mandatory declarations laid down in Article 7 of the notified draft, such as that the product is not a substitute for breast milk. Some delegations asked the Netherlands to clarify whether it would be possible on the basis of the mutual recognition principle, to market products with other designations and whether other relevant EU legislation such as that on nutrition and health claims and on pesticides would apply.

The Commission explained that the draft measure will be examined in accordance with the notification procedure laid down in Directive (EU) 2015/1535, and the procedures laid down in Article 12 of Regulation (EC) No 1925/2006 and in Article 45 of Regulation (EU) No 1169/2011, and that the Dutch authorities will receive the opinions of the Commission within the respective standstill periods.

A.02 Exchange of views of the Committee on a notification by Latvia (2020/322/LV) of a draft Regulation on plants and parts of plants prohibited for use in foods notified to the Commission according to Article 12 of Regulation (EU) No 1925/2006.

On 27 May 2020, 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 and parts of plants that are prohibited for use in foods. Latvia presented the notified text and explained that this draft measure replaces a draft Regulation that had been notified in 2018 and that has been withdrawn. Latvia also explained that the draft Regulation has been amended to include a provision on the application of the mutual recognition procedure on the basis of comments made by the Commission via TRIS.

The Commission explained that the draft measure will be examined in accordance with the procedure laid down in Article 12 of Regulation (EC) No 1925/2006 and that the Latvian authorities will receive the opinion of the Commission within the stipulated standstill period of 6 months.

A.03 Brexit preparedness.

As part of the Commission's actions to ensure readiness for the UK withdrawal 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 invited Member States to pose questions related to actions needed to implement the Withdrawal Agreement. France raised the three questions below, which the Commission addressed as follows:

Q.1 In the notice relating to natural mineral waters, it is specified that products placed on the market in the United Kingdom before the end of the transition period may continue to be distributed on the EU market. Does the same rule apply for example to foodstuffs bearing the identification of a FBO based in the United Kingdom (Cf. article 8 (1) of regulation 1169/2011), or should it be considered that from 1 January 2021 any foodstuff physically entering the EU market will have to bear the identification of a FBO established in the European Union ?

COM reply: The general provisions of the Withdrawal Agreement apply with regard to all goods. Any good that was lawfully placed on the market in the Union or the United Kingdom before the end of the transition period may be further made available on the market of the Union or of the United Kingdom and circulate between these two

markets until it reaches its end-user (See Article 41(1)(a) of the Withdrawal Agreement). Hence, any foodstuff placed on the market in the United Kingdom before the end of the transitional period can lawfully circulate in the EU after 1/1/2021. This is also true for goods that are still physically in the UK after 1 January 2021. Yet, in those cases, the economic operator bears the burden of proof that the product was placed on the market before the end of the transition period in accordance with Article 42 of the Withdrawal Agreement.

Q.2 What about a commodity that would have been the subject of a transfer of ownership before the end of the transition period between its manufacturer in the United Kingdom and an EU distributor but would still be in the UK territory?

COM reply: Such a commodity can circulate in the Union and UK market, if the stage of manufacturing has taken place before 1/1/2021. Existing and individually identifiable goods, manufactured before the end of the transition period, can lawfully circulate in the Union and the UK market after 1/1/2021, when they are the subject matter of a written or verbal agreement between two or more legal or natural persons for the transfer of ownership, any other property right, or possession concerning the good in question, or are the subject matter of an offer to a legal or natural person or persons to conclude such an agreement.

Q.3 With regard to natural mineral waters, will water extracted from the soil of MS and currently on the list of waters recognized in the EU have to follow a specific procedure in order to continue to be marketed in the United Kingdom?

COM reply: Natural Mineral Waters recognized by the responsible authority of a Member State and placed on the market in the EU before the end of the transitional period can lawfully circulate in the UK after 1/1/2021. For goods placed on the EU market after 1 January 2021, it is still unclear what the rules for market access to the UK may be, as the UK has not yet clarified its import rules from 1/1/2021.

A.04 State of play on the implementation of the Farm to Fork Strategy.

The Commission updated Member States on the implementation of the F2F Strategy, which has already started.

The Commission is now reaching out and interacting with a number of relevant parties: EU Member States, stakeholders and third countries.

The Commission has started work on the different initiatives and is committed to the ambitious timelines. For many of these initiatives, and in line with the integrated approach of the strategy, several services of the Commission are involved. This is the case for instance for the two horizontal actions listed in the action plan:

- the Contingency plan, which will be the EU's first mechanism for the coordinated preparation and response to crises that may pose challenges to the EU's food supply chain and where preparatory work has started. Relevant parties will have the opportunity to provide feedback before the end of this year.
- the Framework on sustainable food systems, where preparatory work has started although the initiative is only foreseen for 2023. In this respect, the Commission mentioned the plan to revamp the existing Expert group on general food law into expert group on general food law and sustainability of food systems in order to ensure that all relevant experts from Member States can attend as sustainability of food systems is broader than food law.

The Commission then updated Member States:

- on the CAP recommendations (to be adopted before the end of the year): a structured dialogue with Member States is crucial in this process. Bilateral meetings with the Member States will be organised with the involvement of the relevant Commission services. They will take place before the recommendations are adopted, and then again, before the adoption of the national strategic plans.
- on the Code of Conduct, whose planed delivery date is Q2 2021. The code will address both environmental and health issues; it is specifically addressing the 'middle' part of the food chain (such as food companies, retailers) and it will be one of the first concrete outcomes of the F2F strategy. It will be developed together with relevant stakeholders. The first meeting with stakeholders should take place towards end of October/beginning of November.

Finally, the Commission updated Member States on the next steps regarding the labelling actions announced in the Farm to Fork Strategy related to front-of-pack nutrition labelling, nutrient profiles, origin labelling and date marking, targeting food processing, food consumption and food waste. The Commission explained that the preparatory work for the four proposals will follow the same timeline and better regulation process. The Commission explained that an impact assessment will be carried out for the different initiatives and, as a first step in the process, an inception impact assessment will be published in the Autumn for public feedback. As a next step, a study will be launched beginning 2021 to support the impact assessment, while also other studies and advice from experts are planned. In 2021, a public consultation will take place, along with consultations of stakeholders and national authorities. Finalisation of the impact assessment is scheduled for beginning 2022, while the adoption of the proposals should take place as scheduled by Q4 2022.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Directive 2002/46/EC of the European Parliament and of the Council as regards magnesium citrate malate and nicotinamide riboside chloride used in the manufacture of food supplements and as regards the units of measurement used for copper.

The draft Commission Regulation aims at including the substances nicotinamide riboside chloride and magnesium citrate malate in Annex II to Directive 2002/46/EC and thereby permitting their use in the manufacture of food supplements. The substances have received a favourable scientific assessment by the European Food Safety Authority and are both included in the Union list of novel foods laid down in Commission Implementing Regulation (EU) 2017/2470. The draft measure also proposes to amend the units for copper in Annex I to Directive 2002/46/EC to align them with those required for labelling purposes according to Regulation (EU) 1169/2011.

The Commission took note of a delegation's comment to ensure the best possible working practice for requests for new nutrient sources that are also novel foods. The Commission explained that it is developing an e-submission tool in the context of the Transparency Regulation that will improve efficiency and coherence between the novel foods legislation and that related to specific categories of foods.

Some delegations requested modifications to recitals 7 and 13 and to the title of the draft measure to ensure clarity and coherence, which the Committee agreed to. The Commission informed the delegations of its intention to obtain the vote on this draft Commission Regulation by written procedure. The delegations gave their agreement to proceed in that way.

Vote taken by written procedure: positive opinion.

B.02 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 botanical species containing hydroxyanthracene derivatives.

The Commission presented the revised draft measure to Member States and reminded the Committee that the EU Reference Laboratory on mycotoxins and plant toxins (EURL) had been asked for assistance in determining validated analytical methods and limits of quantification (LOQs) for hydroxyanthracene derivatives (HADs) in the different botanical preparations. The Commission informed the Committee of the outcome of the technical discussion held on the basis of the EURL's report on the available analytical methods for the quantification of HADs, in the context of the working group on fortified foods and food supplements. The Commission also informed the Committee of the result of a targeted stakeholder consultation that had been carried out on the proposed harmonised LOQs for HADs.

During the exchange of views, some Member States raised concerns on the draft measure arguing, in particular that it would pose enforcement difficulties, as the concerned HADs could possibly be found in some plants and preparations thereof, including common vegetables. Most of the Member States expressed their support for the revised draft measure and the proposed approach to define the presence of HADs at the LOQs, while asking for some clarification on:

- The scope of the measure, in particular, whether the measure would apply to food to which substances are added for flavouring purposes;
- The analytical test methods to be used for the quantification of the total amount of HADs in aloe products;
- The applicability of the proposed LOQs.

The Commission informed Member States that the European Food Safety Authority would be asked to carry out a literature search on the HAD-content of commonly consumed vegetables in order to better understand the possible impact of the proposed LOQs on the mentioned products.

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

- As stipulated in Article 1(3)(d) of Regulation (EC) No 1925/2006, Regulation (EC) No 1925/2006 shall apply without prejudice to the Union legislation concerning flavourings. The draft measure is in accordance with the scope of Regulation (EC) No 1925/2006 and the procedure under Article 8 of that Regulation. The scope of the prohibition therefore covers the use of substances for nutritional or physiological purposes, without regulating other possible uses, such as the addition of a substance for flavouring purposes to food.

- Practical methods that quantify the total HAD-content in Aloe preparations could not be identified by the EURL in its report. In the absence of these methods aloin, the most prominent HAD found in Aloe Species, is typically used as a marker to quantify the HAD-content in Aloe preparations.
- The LOQs apply to the product as consumed. More precisely, the LOQs apply to the product ready for use after preparation in accordance with the manufacturer's instructions. In case a range is provided, the highest concentration is to be used. In the absence of instructions for use, the LOQs apply to the product as sold.

After some discussion, the Committee agreed to the following statement:

"Presence of certain hydroxyanthracene derivatives in food

In its scientific opinion[1], the European Food Safety Authority concluded that the hydroxyanthracene derivatives aloe-emodin, emodin and danthron as well as aloe extracts containing hydroxyanthracene derivatives are genotoxic and can cause cancer in the intestine.

Considering the severe harmful effects on health associated with exposure to aloe-emodin, emodin, danthron and aloe extracts containing hydroxyanthracene derivatives in food, and that no daily intake of hydroxyanthracene derivatives that does not give rise to concerns for human health could be set, such substances should not be added to food or used in the manufacture of food i.e. should not be present in the products.

The Committee concluded that products ready for use after preparation in accordance with the manufacturer's instructions containing an analysed level higher than or equal to 1 ppm aloe-emodin and/or 1 ppm emodin and/or 1 ppm aloin A + aloin B provide clear evidence of presence of these substances in the products and are therefore of concern for public health. The sum of the analysed contents of aloin A and aloin B can be used to quantify the total HAD content in preparations from the leaf of Aloe species, since aloin A and B are the most commonly occurring HADs in Aloe species. Measures as regards such products should be taken to ensure a high level of human health protection.

The Commission stressed, based on the advice of the European Reference Laboratory on mycotoxins and plant toxins, that the level of 1ppm for aloe-emodin/emodin and the level of 1 ppm for the sum of aloin A and aloin B are for the time being the lowest levels that can be reliably quantified in laboratories across the EU and can therefore be put forward as limits of quantification in an EU harmonised risk management approach.

The Commission informed the delegations of its intention to obtain the vote on this draft Commission Regulation by written procedure. The delegations gave their agreement to proceed in that way."

Vote taken by written procedure: positive opinion.

[1] https://www.efsa.europa.eu/en/efsajournal/pub/5090

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.

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 carbohydrate solutions and the contribution to the improvement of physical performance during a high-intensity and long-lasting physical exercise (Question No EFSA-Q-2017-00621). The claim was submitted pursuant to Article 13(5) and has received a favourable assessment by the European Food Safety Authority (EFSA). Accordingly, it should be authorised.

The Commission presented the draft Regulation and reminded the delegations of the discussions on this claim in the context of a working group meeting, where it was last discussed. Some delegations raised concerns about the authorisation of this claim as presented in this draft Regulation. The main concerns related, in particular, to the kind of products that could use this claim and how it could be ensured that only trained adults performing high-intensity and long-lasting physical exercise would be targeted by the claim and consume these products. Other concerns related to the clarity of the conditions of use, particularly regarding the carbohydrates and/or combinations of carbohydrates that can be used to obtain the claimed effect.

Further to this exchange of views, the Commission informed the delegations that it would adapt the draft measure in line with the comments that were raised. Finally, the Commission confirmed that the revised draft Commission Regulation would be shared with the Member States again before proceeding with the authorisation of this claim.

M.01 CJUE in case Lactalis C-485/19

The Commission presented to Member States the ruling of the CJUE in case Lactalis C-485/19, which was published on 1 October 2020.