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Health and Food Safety Directorate General

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Standing Committee on Plants, Animals, Food and Feed
Section *Novel Food and Toxicological Safety of the Food Chain*
27 February 2023

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SUMMARY REPORT

A.01 Statement on cannabidiol as novel food.

At the request of one Member State and in collaboration with the other Member States the Commission presented the following statement on cannabidiol as novel food, which was endorsed by the Committee:

The hemp plant (Cannabis sativa L.) contains more than 100 different cannabinoids, the most common ones being cannabidiol (CBD) and its precursor acidic form cannabidiolic acid (CBD and CBDa respectively), cannabigerol (CBG), cannabinol (CBN), cannabichromene (CBC), and delta-9-tetrahydrocannabinol and its precursor acid form (Δ9-THC and Δ9-THCa respectively).

In its judgment in case C-663/18[1], the Court of Justice of the European Union concluded that cannabidiol (CBD) should not be considered as a drug within the meaning of the United Nations Single Convention on Narcotic Drugs of 1961[2] insofar as it does not have a psychotropic effect. The Commission therefore, considers that cannabidiol can be considered as 'food', provided that the other conditions of Article 2 of the General Food Law[3] are met.

In accordance with Regulation (EU) 2015/2283 (the 'Novel Food Regulation')[4], foods for which a history of human consumption to a significant degree within the Union before 15 May 1997 cannot be demonstrated, are novel and may not be placed on the market within the Union as such, or used in foods until they have been authorised and included in the Union list of authorised novel foods.

A history of consumption to a significant degree within the EU prior to 15 May 1997 has not been demonstrated for CBD or any other cannabinoids, or products containing either CBD and/or other cannabinoids derived from the Cannabis sativa L. plant. Therefore, with the exception of the THC cannabinoids, they are considered novel foods until acceptable and verifiable evidence to the contrary is provided. The THC cannabinoids are considered as a drug within the meaning of the United Nations Single Convention on Psychotropic Substances of 1971 and can therefore not be considered as "food". In the EU legislation the presence of THC in food is regulated by the legislation on contaminants.

The Commission has received over 190 applications for the authorisation of CBD and extracts of Cannabis sativa L. and derived products containing cannabinoids under the Novel Food Regulation. Of these applications, so far 20 have been considered by the Commission to be valid and are currently being evaluated by EFSA. In a statement[5] of June 2022, EFSA identified several potential hazards and determined that many data gaps relating to possible health effects need to be filled before the evaluations of the safety of CBD and hemp extracts can progress.

At present, there has been no authorisation of CBD, of any other cannabinoids, nor of products containing either CBD and/or other cannabinoids derived from the Cannabis sativa L. plant under Regulation (EU) 2015/2283 on novel foods.

Member States have the primary responsibility for the correct application, implementation and enforcement of EU legislation.

[1] Judgment of the Court in Case C-663/18 of 19 of November 2020, B S and C A (Commercialisation du cannabidiol - CBD), ECLI:EU:C:2020:938.

[2] United Nations Treaty Series, vol. 978, No 14152.

[3] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1.

[4] Regulation (EU) 2015/2283 of 25 November 2015 on novel foods. OJ L327, 11.12.2015, p. 1.

[5] EFSA Journal 2022;20(6):7322

A.02 Feedback on the recent work of the PAFF Working Group on Food Contact Materials (FCM).

The Commission services provided feedback on the discussions of the FCM Experts on 9 and 10 February. A possible approach for revising Regulation (EC) No 1935/2004 was presented in more detail. The exploratory work is being divided in 6 pillars, three of these pillars (*shifting the attention to the final materials, a tiered system for prioritising the Risk Assessment of substances, and a new pillar for analytical methods*) were discussed in more depth. Commission services also explained the possible grouping of materials into six groups – materials would be grouped on the basis of the need for a common regulatory approach, rather than their technical definition or common naming. Short attention was also given to sustainable food contact material, including the work on possible rules for the reuse of packaging materials. The Commission also discussed shortly on Regulation (EU) No 284/2011, which would stay unchanged. However, the Commission services are preparing a change to the TRACES reporting system.

Several amendments to Regulation (EU) No 10/2011 were discussed, as well as the present state of implementation of Regulation (EU) 2022/1616. The implementation of the Register under Article 24 thereof is momentarily delayed due to inconsistent data; the work on preparing the individual authorisation decisions is making good progress. Also the guidance on Annex II to that Regulation was discussed with a view to help the Member States preparing for the audits in accordance with Article 25 of the Regulation.

The agenda and slides for the meeting are available in the FCM document library: https://food.ec.europa.eu/safety/chemical-safety/food-contact-materials/fcm-document-library_en

A.03 EFSA Report on the 2021 results from the monitoring of veterinary medicinal product residues and other substances in live animals and animal products.

EFSA presented the main elements of the report to the Committee. In addition, results can be browsed via the EFSA interactive data visualisation tool that shows the results in more details. The Commission informed Member States that the report is also published on the DG SANTE website.

A.04 Discussion on the setting of regulatory levels for acrylamide in food and of maximum levels of glycidyl fatty acid esters and 3-MCPD fatty acid esters in certain compound foods. Follow-up to the discussion in the WG of Industrial and Environmental Contaminants of 16 February 2022.

Acrylamide

The Committee was informed of the discussions on acrylamide at the meeting of the WG. A difficulty that has arisen is that the food categorisation of the recent occurrence data (*sampling years 2020 and 2021*) from the EFSA database differs from the food categorisation for the occurrence data from the EFSA database for the sampling years 2016-2019. The food categories of the two data sets are not directly comparable which does not facilitate the assessment of the suggested new benchmark levels and maximum levels on the basis of the most recent occurrence data. Work is ongoing to find a solution to this problem to ensure that technical discussions on the suggested new benchmark levels and maximum levels can be finalised by autumn 2023.

3-MCPD esters in infant formula and follow-on formula

The foreseen review of maximum levels for 3-MCPD esters in infant formula, follow-on formula and foods for special medical purposes intended for infants and young children and young child formula (powder and liquid) is ongoing and based on the most recent occurrence data (*sampling years 2020 -2021*). It is evident from these data that the current maximum level should be lowered to continue ensuring a high level of human health protection.

3-MCPD fatty acid esters and glycidyl fatty acid esters in compound foods

The establishment of possible maximum levels for 3-MCPD fatty esters and glycidyl fatty acid esters in compound foods takes into account the occurrence data available in the EFSA database, including the most recent data. The same issue as regards the comparability of the data sets 2009-2019 and the more recent data 2020-2021 as mentioned for acrylamide was highlighted. Although it has still to be decided for which compound foods a maximum level should be established, the possible setting of maximum levels for baby foods and processed cereal based foods for infants and young children is to be considered in priority. However, a major drawback is the limited availability of occurrence data, thereby necessitating the establishment of maximum levels taking into account other parameters such as the typical vegetable oil content. In that context it was suggested that it would be appropriate for competent authorities and food business operators to perform on short notice a targeted monitoring on the presence of 3-MCPD fatty acid esters and glycidyl fatty acid esters and provide these data directly to the Commission (*in addition to the submission to the EFSA database*)

to enable the use of these data for the further discussions on maximum levels for 3-MCPD fatty acid esters and glycidyl fatty acid esters for baby foods and processed cereal based foods for infants and young children. It is foreseen to finalise the technical discussions on maximum levels for 3-MCPD fatty acid esters and glycidyl fatty acid esters for baby foods and processed cereal based foods for infants and young children and possible other compound foods by autumn 2023.

A.05 Information and exchange of views on the outcome of the technical meeting of 19 January 2023 on the enforcement approach in case of findings of genotoxic carcinogenic substances in food.

The Committee was informed on the outcome of the technical meeting of 19 January 2023 with Member States on the enforcement approach in case of findings of genotoxic carcinogenic substances in food, and on the next steps for this work. At the meeting, there was a large agreement on the overall proposed enforcement approach but still divergent views expressed on certain related topics. Comments from nine Member States were also received in writing. The document will be updated by the Commission services, taking into account all this feedback. A new technical meeting will be convened before the summer break to continue the discussion, with the aim to conclude on the enforcement approach. It was considered important to clarify that the proposed enforcement approach(es) would not be applicable in case it concerns genotoxic carcinogenic contaminants for which Maximum Levels have been established in certain food commodities above the Limit of Quantification (LOQ), or if it concerns non-regulated genotoxic carcinogenic contaminants, whose presence in food is unavoidable.

A.06 Exchange of information on the reporting of cases of poisoning related to the presence of lectins in food.

The Commission services were informed of outbreaks of lectin poisoning in the past years. Lectins are compounds that are naturally present in certain beans (and other vegetables) and can cause symptoms in case these beans are insufficiently cooked. While this is not a new problem, it was highlighted that, with the transition towards more plant-based diets, such poisoning could occur more frequently and therefore it would be appropriate to address the issue. Lectins are plant toxins falling under the EU legislation on contaminants. Some Member States confirmed recent cases of poisoning related to the presence of lectins. Therefore, it was found appropriate to request the European Union Reference Laboratory (EURL) for Mycotoxins and Plant toxins to provide an overview of the available methods of analysis for lectins in food and to perform further work on the analytical aspects within the EURL/NRL network, while requesting a risk assessment by EFSA on the risks for human health related to the presence of lectins in food. The Committee was informed that a follow-up discussion will take place at the Working Group Agricultural Contaminants scheduled for 21 March 2023.

A.07 Information and exchange of views on the upcoming review of Commission Implementing Regulation (EU) 2021/1533 of 17 September 2021 imposing special conditions governing the import of feed and food originating in or dispatched from Japan following the accident at the Fukushima nuclear power station and repealing Implementing Regulation (EU) 2016/6.

The committee was informed on the next steps and provisional timetable for the upcoming review of Commission Implementing Regulation (EU) 2021/1533. Several Member States proactively expressed their views on the review.

A.08 Update and exchange of views on different topics related to contaminants in food.

Information was provided on the ongoing discussions on the review of the maximum level for perchlorate in green beans. The plan is to finalise the technical discussion on the maximum levels for T-2 and HT-2 toxin and deoxynivalenol in food at the meeting of the WG Agricultural Contaminants on 21 March 2023. At that meeting, also a discussion on the enforcement of transitional measures provided for in Regulation (EU) 2020/2040 on maximum levels for pyrrolizidine alkaloids will take place in view of a harmonised approach. Member States were also reminded to provide by 30 June 2023 the results of the investigations undertaken and to inform on the progress with the application of prevention measures to prevent contamination by ergot sclerotia and ergot alkaloids in rye and rye milling products and ergot alkaloids in milling products of barley, wheat, spelt and oats grains. The Commission informed that a targeted stakeholder consultation was launched regarding a proposal for maximum levels (MLs) for nickel in food and for a monitoring Recommendation on nickel in food. Stakeholders have been requested to support their comments with occurrence data and to send them to the Commission by 7 April 2023. The Commission informed that the EFSA opinion on mineral oil hydrocarbons in food has been endorsed by the EFSA CONTAM Panel. The public consultation on the opinion will be launched in the coming weeks. The final opinion is intended to be adopted in July 202,3 at the latest.

The Commission informed on the conclusions of the 2023 EFSA scientific report on the dietary exposure to heavy metals and iodine via the consumption of seaweeds and halophytes in the European population. It expressed the intention to start discussions on possible MLs for heavy metals in seaweed. In view of the high concentrations of heavy metals which occur in certain seaweed species, also consumption advice for seaweed should be considered. Furthermore the consumption of certain seaweed species could lead to too high intakes of iodine. The Commission will consider how to best address this issue and take the appropriate follow-up measures.

A.09 Exchange of views and possible opinion of the Committee on a draft Commission Recommendation (EU) on the monitoring of food additive and food flavouring intake.

The Commission presented the draft Recommendation and its Annex, explained its content and opened the floor for comments. During the discussion, Belgium indicated that it could not support the proposal and asked to include the following declaration in the report of the meeting: "*Belgium has too many concerns and questions about the current draft Commission Recommendation (EU) on the monitoring of food additive and food flavouring intake. Therefore we are not ready to endorse it and further discussion is needed. There are concerns related to the scope and the relation between the recommendation and the food additive and flavouring regulations, about the budgetary impact, about the continued lack of EURL and analytical methods for food*

additives and food flavourings. Belgium remains however engaged to continue work on national level to comply with article 27.1. of the food additive regulation."

The concern regarding the dearth of an EURL was shared by two other Member States. One Member State raised concern regarding the impact on resources stemming from the implementation of the Recommendation. The Commission explained that the Recommendation was developed following the feedback from Member States that guidance for the monitoring is necessary. In addition, it was explained that comments regarding the impact on resources were taken into account in the current proposal. The Commission acknowledges the difficulties to develop and implement analytical methods in the area of food additives and food flavourings and considered this among the reasons for providing the methodology in the form of a Commission Recommendation instead of an implementing act. In addition, the Commission will soon initiate the process to establish an EURL for food additives. The Recommendation was endorsed by the Committee.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Regulation (EU) 2022/… [XXX] as regards maximum levels of cadmium in tiger nuts and certain cultivated fungi.

The Commission presented the draft act and explained its contents. The Regulation would increase the maximum levels (MLs) for cadmium in tiger nuts and cultivated fungi other than common mushroom (*Agaricus bisporus*), Shiitake or Oyster mushrooms on the basis of the most recent occurrence data, taking into account the 'As Low As Reasonably Achievable' principle. The species concerned by the proposal only represent a limited contribution to the total consumer exposure to cadmium. A Member State commented that is does not support the draft act, because the overall consumer exposure to cadmium is too high and should thus be reduced. It fears that in some cases tiger nuts are consumed in large amounts. As regards the concerned fungi it believes that the cadmium concentration could be mitigated by a careful selection of growth media and fertilisers. It also pointed to an increased consumption of fungi as replacement of meat. Another Member State expressed its support to the proposal and explained that tiger nuts are mainly consumed in a processed form as drinks, in which the concentrations of cadmium are low. It also pointed to the fact that the previous approach of applying the ML for radishes to tiger nuts was not correct, as tiger nuts are a different type of plant. Therefore a separate ML for tiger nuts needed to be established, on the basis of data for tiger nuts alone.

The Commission confirmed that the exposure to cadmium from the consumption of tiger nuts and fungi other than common mushroom (*Agaricus bisporus*), Shiitake or Oyster mushrooms is very limited in comparison with the exposure from the rest of the diet. Although mitigation measures via the selection of fertilisers and growth media are recommended, for the concerned species it would be very challenging to reach acceptable compliance rates. It would also be difficult to explain that for Oyster mushroom (*Pleurotus ostreatus*) an ML of 0.15 mg/kg applies, while for *Pleurotus enryngii*, the ML of 0.050 mg/kg for other cultivated fungi would apply. Following a comment received by a Member State, the proposal was amended to ensure that each ML is expressed with two significant numbers.

Vote taken: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation correcting Implementing Regulation (EU) 2017/2470 as regards the inclusion of 'Phosphated distarch phosphate produced from wheat starch' in the Union list of novel foods.

The Commission presented the draft act correcting Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods. The measure is intended to correct an error in the Union list of novel foods, related to the novel food '*Phosphated distarch phosphate produced from wheat starch'* which, while being already authorised, was not included in the Union list when it was initially established.

Vote taken: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) authorising the placing on the market of iron milk caseinate as a novel food and amending Commission Implementing Regulation (EU) 2017/2470.

The Commission presented to the Committee the draft Commission Implementing Regulation (EU) authorising the placing on the market of iron milk caseinate as a novel food. The measure, which is underpinned by a favourable EFSA opinion, authorizes the use of iron milk caseinate in a number of foods intended for the general population and in food supplements intended for the general population but excluding infants and young children.

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use of the novel food '2´-Fucosyllactose'.

The Commission presented to the Committee the draft Commission Implementing Regulation (EU) authorising the change in the conditions of use of the novel food '2´-Fucosyllactose' to remove the obligatory use of it in a 2:1 ratio with the authorised novel food Lacto-*N*-Neotetraose when they are used in combination in infant formula, follow on formula and milk based drink intended for young children. A recent positive EFSA opinion on the use of each of these oligosaccharides alone in food supplements at the currently authorised maximum use levels supports the proposed changes.

Vote taken: Favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use of the novel food 'Lacto-*N*-neotetraose' and the specifications of Lacto-*N*-neotetraose (microbial source) produced with the derivative strains PS-LNnT-JBT and DS-LNnT-JBT of Escherichia coli BL21(DE3).

The Commission presented to the Committee the draft Commission Implementing Regulation (EU) authorising the change in the conditions of use of the authorised novel food 'Lacto-*N*-Neotetraose' to remove the obligatory use of it in a 1:2 ratio with the authorised novel food 2´-Fucosyllactose when they are used in combination in infant formula, follow on formula and milk based drink intended for young children. A recent positive EFSA opinion on the use of each of these oligosaccharides alone in food

supplements at the currently authorised maximum use levels supports the proposed changes.

Vote taken: Favourable opinion.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) 2017/2470 as regards as regards the specifications of the novel food 'protein extract from pig kidneys'.

The Commission presented to the Committee the draft Commission Implementing Regulation (EU) authorising the change in the specifications of the novel food '*protein extract from pig kidneys'* to allow for its production using an acetone wash based process, and the use of a different method to measure the Diamine Oxidase activity contained in the novel food. No EFSA opinion was deemed necessary for this draft act as acetone is an authorised extraction solvent routinely used for the production/extraction of foods and has been assessed by EFSA in the context of the evaluation of another novel food produced and used in an identical manner (*and resulting in identical intakes*) as the pig kidney extract.

Vote taken: Favourable opinion.

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) 2017/2470 as regards the specifications of the novel food '2'-Fucosyllactose' (microbial source) to authorise its production by a derivative strain of Corynebacterium glutamicum ATCC13032.

The Commission presented to the Committee the draft Commission Implementing Regulation (EU) authorising the change in the specifications of the novel food 2´-Fucosyllactose produced microbiologically to allow for its production by a derivative strain of *Corynebacterium glutamicum* ATCC13032 on the basis of a positive EFSA opinion.

Vote taken: Favourable opinion.

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) authorising the placing on the market of 6'-Sialyllactose sodium salt produced by derivative strains of *Escherichia coli* BL21 DE3 as a novel food and amending Commission Implementing Regulation (EU) 2017/2470.

The Commission presented to the Committee the draft Commission Implementing Regulation (EU) authorising 6'-Sialyllactose sodium salt as a novel food to be used in a number of foods intended for the general population and in food supplements intended for the general population excluding infants and young children, on the basis of a positive EFSA opinion.

Vote taken: Favourable opinion.

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) authorising the placing on the market of aqueous ethanolic extract of *Labisia pumila* as a novel food and amending Implementing Regulation (EU) 2017/2470.

The Commission presented to the Committee the draft Commission Implementing Regulation (EU) authorising the placing on the market of aqueous ethanolic extract of *Labisia pumila* as a novel food to be used in food supplements as defined in Directive 2002/46/EC for the adult population, excluding pregnant and lactating women, on the basis of a positive EFSA opinion.

Vote taken: Favourable opinion.

B.10 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) authorising the placing on the market of cellobiose as a novel food and amending Implementing Regulation (EU) 2017/2470.

The Commission presented to the Committee the draft Commission Implementing Regulation (EU) authorising the placing on the market of cellobiose as a novel food to be used in a number of foods, on the basis of a positive EFSA opinion.

Vote taken: Favourable opinion.

B.11 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use of the novel food *infusion from coffee leaves of Coffea arabica L. and/or Coffea canephora Pierre ex A. Froehner.*

The Commission presented to the Committee the draft Commission Implementing Regulation (EU) authorising the amendment of the conditions of use of the traditional food from a third country 'infusion from coffee leaves of *Coffea arabica* L. and/or Coffea canephora Pierre ex A. Froehner'. In particular, this amendment concerns the extension of use of the infusion from coffee leaves of *Coffea arabica* L. and/or *Coffea canephora* Pierre ex A. Froehner to additional foods intended for the general population. As the requested extensions of use are not liable to have an effect on human health, a safety evaluation by EFSA was not necessary.

Vote taken: Favourable opinion.

B.12 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use of the novel food *Yarrowia lipolytica* yeast biomass.

The Commission presented to the Committee the draft Commission Implementing Regulation (EU) authorising the amendment of the conditions of use of the novel food *Yarrowia lipolytica* yeast biomass. In particular, this amendment concerns the extension of use of the novel food in meal replacements for weight control intended for the adult population. The decision is based on a positive EFSA opinion.

Vote taken: Favourable opinion.

B.13 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) amending the Annex to Regulation (EU) No 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards specifications for mono- and diglycerides of fatty acids (E 471).

The Commission presented to the Committee the draft Commission Regulation for the revision of the specifications of mono- and diglycerides of fatty acids (E471) following its re-evaluation by the Authority. On September 2021, EFSA recommended to reduce the maximum levels for arsenic, lead, mercury, cadmium and include maximum levels for 3-MCPD and 3-MCPD fatty acid esters (*expressed as 3-MCPD*), acid erucic and glycidyl fatty acid esters (*expressed as glycidol*). A transitional period will be granted to allow the manufacturers of this food additive to lower the levels of glycidyl fatty acid esters. During the same transitional period, the manufacturers are also allowed to use the food additive (E 471) lawfully placed on the market before the entry into force of this Regulation and the food containing such additive are allowed to continue to be placed on the market during this period until their date minimum durability or 'use by' date. It was clarified that the food additive (E 471) not complying with the minimum level of glycidyl fatty acid esters (*expressed as glycidol*) set out in this Regulation for use in foods for infants and young children are not allowed to be added to such foods after the date of the entry into force. Several Member States asked for some guidance on the implementation of the transitional periods, to ensure clarity for the Food Business Operators and an effective EU harmonisation.

Vote taken: Favourable opinion.

B.14 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of polyglycerol polyricinoleate (E 476) and the Annex to Commission Regulation (EU) No 231/2012 as regards specifications for glycerol (E 422), polyglycerol esters of fatty acids (E 475) and polyglycerol polyricinoleate (E 476).

The Commission presented the draft Commission Regulation authorising an extension of use of polyglycerol polyricinoleate (E 476) in food category 03 'Edible ices' and in food category 12.6 'Sauces' and amending the specifications for glycerol (E 422), polyglycerol esters of fatty acids (E 475) and polyglycerol polyricinoleate (E 476) as a follow-up of their re-evaluations by EFSA. EFSA concluded that the proposed extension of use for E 476 would not give rise to a safety concern. For glycerol (E 422), EFSA concluded that the current specifications were to be adapted in particular by reducing the maximum limits for toxic elements, by deleting the identification method based on acrolein formation during heating, by deleting the test for the presence of acrolein, by including a maximum limit for acrolein and by modifying the definition of glycerol (E 422). For polyglycerol esters of fatty acids (E 475) and polyglycerol polyricinoleate (E 476), EFSA concluded that the current specifications were to be adapted in particular by reducing the maximum limits for toxic elements, by including maximum limits for impurities and constituents of safety concern and by modifying the definitions of polyglycerol esters of fatty acids (E 475) and polyglycerol polyricinoleate (E 476). It is therefore appropriate to authorise the extension of use of polyglycerol polyricinoleate (E 476) and to amend the specifications for glycerol (E 422), polyglycerol esters of fatty acids (E 475) and polyglycerol polyricinoleate (E 476). A transitional period is granted to allow the manufacturers of the food additive

polyglycerol esters of fatty acids (E 475) to lower the levels of glycidyl fatty acid esters (expressed as glycidol). During the same transitional period, the manufacturers are allowed to use the food additives (E 422, E 475 and E 476) lawfully placed on the market before the entry into force of this Regulation and the foods containing such food additive may continue to be placed on the market during the transitional period and to remain on the market until their date minimum durability or 'use-by' date. Several MS asked for some guidance on the implementation of the transitional periods, to ensure clarity for the Food Business Operators and effective EU harmonization.

Vote taken: Favourable opinion.

B.15 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision refusing the Authorisation for the inclusion of Prosmoke BW 01 in the Union list of authorised smoke flavouring primary products.

The Commission presented the draft Commission Implementing Decision refusing the Authorisation for the inclusion of Prosmoke BW 01 in the Union list of authorised smoke flavouring primary products. On 31 March 2022, the Authority (EFSA) adopted its scientific opinion on the safety of Prosmoke BW 01 in accordance with Article 8 of Regulation (EC) No 2065/2003. According to that opinion furan-2(5H)-one was present in all batches of the primary product. Considering that the exposure estimates for furan-2(5H)-one are above the 'Threshold of Toxicological Concern' (TTC) value of 0.0025 μg/kg bw per day for DNA-reactive mutagens and/or carcinogens, the Authority concluded that Prosmoke BW 01 raises a concern with respect to genotoxicity. Therefore, it is appropriate to refuse the authorisation for the inclusion of Prosmoke BW 01 in the Union list of authorised smoke flavouring primary products.

Vote taken: Favourable opinion.

B.16 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Implementing Regulation (EU) No 1321/2013 as regards the name of the holder of the authorisation for 'TradismokeTM A MAX' (Unique Code SF-007).

The Commission presented the draft Commission Implementing Regulation changing the authorisation holder for the smoke flavouring primary product 'TradismokeTM A MAX' as stated in Commission Implementing Regulation (EU) No 1321/2013 establishing the Union list of authorised smoke flavouring primary products. The applicant confirmed that no other changes or amendments to the authorisation were requested and in particular the smoke flavouring primary product TradismokeTM A MAX and the production process remained unchanged. The proposed change is thus purely administrative in nature and therefore does not entail a new safety assessment. Implementing Regulation (EU) No 1321/2013 should be amended accordingly.

Vote taken: Favourable opinion.

C.01 Exchange of views on a draft Commission Regulation (EU) amending Annexes II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards food additives nitrites (E 249-250) and nitrates (E 251-252).

The Commission presented the state of play regarding this draft act. It explained the changes made following the meeting of the Working Party of Governmental Experts on Additives on 31 January – 1 February 2023 and invited Member States to express their views on the draft text. While there was an agreement in principle on the objectives and main provisions, several Member States provided specific comments on some provisions, including provisions for some traditional products and on the appropriate length of a transitional period to minimise the economic impact of the revised conditions of use of nitrites and nitrates. Some Member States stated that they would need some further time to consider the draft text. The Commission asked for any additional comments to be submitted by 10 March 2023 as the intention is to finalise the text and put it on the agenda of the next Committee meeting for a possible opinion.

C.02 Exchange of views on a Commission Implementing Regulation laying down the methods of sampling and analysis for the control of mycotoxins in food and repealing Regulation (EC) No 401/2006.

A final technical discussion on this draft Commission Implementing Regulation is foreseen at the meeting of the WG Agricultural Contaminants on 21 March 2023 in view of its submission for a possible opinion at a next meeting of the Committee.

C.03 Exchange of views on a Commission Implementing Regulation laying down the methods of sampling and analysis for the control of plant toxins in food and repealing Regulation (EU) No 2015/705.

A final technical discussion on this draft Commission Implementing Regulation is foreseen at the meeting of the WG Agricultural Contaminants on 21 March 2023 in view of its submission for a possible opinion at a next meeting of the Committee**.**