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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 19 October 2022

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SUMMARY REPORT

A.01 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 of 19 and 20 September. During that meeting the upcoming amendments to Regulation (EU) No 10/2011 were discussed. The text of the 16th amendment was finalised, it was explained that the 17th amendment would be used primarily to align Regulation (EU) No 10/2011 and (EU) 2022/1616 but that it would also have other functions regarding the maintenance of the text of Regulation (EU) No 10/2011. The 18th amendment is to introduce new limits for stryrene (likely between 10-50 ppb) and titanium dioxide. The Working Group also briefly discussed enforcement actions (bamboozling and Regulation (EU) No 284/2011), explained the state of play of the planned revision of the FCM framework lagislation, and shortly addressed a number of miscellaneous points under AoB. The second day was devoted to a hands-on discussion of the main procedures under Regulation (EU) 2022/1616.

A.02 Approval of the 2022 Member States' plans for monitoring of residues in accordance with Directive 96/23/EC.

The Commission informed the Committee that the Member States' and Northern Ireland's residue monitoring plans for animals and animal products have been evaluated by DG Health and Food Safety, as foreseen by Directive 96/23/EC. This evaluation also included the review of the plans by the European Union Reference Laboratories. The Commission recommended the approval of all 27 Member States' and Northern Ireland's residue monitoring plans for 2022. No comments or objections were raised by the Member States during the meeting and the Committee approved the 27 Member States' and Northern States' and Northern Ireland's residue monitoring plans for 2022.

A.03 Clarifications on the joint statement of 21 April 2022 of the Member States regarding the presence of Mineral Oil Aromatic Hydrocarbons (MOAH) in food, including food for infants and young children.

As regards their joint statement of 21 April 2022 regarding the presence of Mineral Oil Aromatic Hydrocarbons (MOAH) in food, including food for infants and young

children, the Member States agreed to clarify that the scope covers all foods, the limits will be applied to the products 'as sold', regardless of the source of MOAH. The total MOAH concentration covers the fraction of MOAH \geq C10 to \leq C50. The Member States also agreed to further specify the fat content of the products to which the limits of 1 and 2 mg/kg are applicable. For the limit of 0.5 mg/kg, no further specifications were needed:

- 0.5 mg/kg for dry foods with a low fat/oil content ($\leq 4\%$ fat/oil)
- 1 mg/kg for foods with a higher fat/oil content (>4% fat/oil, \leq 50% fat/oil)
- 2 mg/kg for fats/ oils or foods with >50% fat/oil

The joint statement of 21 April 2022 by the Member States remains fully valid, with the above clarifications.

A Member State informed that the food sector of oil producers raised concerns on the statement and it informed about an ongoing study on the toxicity of 1-2 ring MOAH. The Commission informed that 1-2 ring MOAH will also be assessed in the context of the upcoming EFSA opinion. As regards this opinion some delays have occurred. The endorsement of the opinion is now scheduled for the EFSA CONTAM Panel meeting of January 2023 and the launch of a public consultation is foreseen for February 2023.

A Member State enquired on the way the statement would be applied in case the MOAH originates from an authorised additive or food contact material. The Commission explained that the statement applies regardless of the source of the MOAH. Once the new EFSA opinion will be available, it will be evaluated whether changes are needed for the requirements for certain additives or food contact materials.

A Member State informed that food business operators expressed concerns on how the statement will be implemented by Member States in advance of the publication of the EFSA opinion and on the reliability of the analytical methods.

The Commission informed that the Commission's Joint Research Centre drafted an update of the standard operating procedure (SOP) for the analysis of mineral oil hydrocarbons in infant formulae, which was validated via a collaborative trial. It was encouraging to see that quite some labs reached the required reproducibility and accuracy requirements. The updated SOP will be published in the coming weeks (post meeting note: the updated SOP has been published in the meanwhile and is available under the following link: <u>https://joint-research-centre.ec.europa.eu/eurl-food-contact-materials/eurl-fcm-test-methods_en</u>). Furthermore an update of the JRC Guidance will be circulated for comments by the national reference laboratories in November 2022, with a foreseen publication in the beginning of 2023. It will contain Guidance on:

- the integration of total MOAH,
- the reporting of total MOAH, without a further need to report on the MOAH fractions,
- the calculation of the LOQ for total MOAH.

A.04 Information on the procedure to be followed in case of a nuclear accident at of the Zaporizhzhia Power Station (Ukraine).

The Commission representative informed the Committee that it is closely following the potential nuclear risks in the context of the war in Ukraine. The provisions provided for in <u>Council Regulation (Euratom) 2016/52 of 15 January 2016 laying down maximum</u>

permitted levels of radioactive contamination of food and feed following a nuclear accident or any other case of radiological emergency were highlighted. In particular attention was drawn to the provisions of Article 3 of that Regulation, which provide that, when the Commission receives official information on a nuclear accident or on any other case of radiological emergency which is likely to lead to or has led to significant radioactive contamination of food and feed, an implementing Regulation shall be adopted rendering applicable pre-established maximum permitted levels to the potentially contaminated food or feed that could be placed on the market.

A.05 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 targeted stakeholder consultation on the draft Commission Implementing Regulation was conducted between 20 July and 2 September 2022. Comments from several stakeholder organisations were received. The analytical performance criteria were extensively discussed at the most recent workshop of the EURL/NRL network "Mycotoxins and Plant Toxins" in Wageningen on 4-5 October 2022. A discussion on the draft Implementing Regulation shall take place at the meeting of the Working Group on Agricultural Contaminants scheduled on Monday 24 October, taking into account the comments from Member States, stakeholders and the outcome of the discussions at the EURL/NRL workshop, with a view to finalise the technical discussions and submit the draft Commission Implementing Regulation for an opinion at a next meeting of the Committee.

A.06 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 targeted stakeholder consultation on the draft Commission Implementing Regulation took place between 20 July 2022 and 2 September 2022. Comments from several stakeholder organisations were received. The analytical performance criteria were extensively discussed at the most recent workshop of the EURL/NRL network "Mycotoxins and Plant Toxins" in Wageningen on 4-5 October 2022. A discussion on the draft Implementing Regulation shall take place at the meeting of the Working Group Agricultural Contaminants on Monday 24 October, taking into account the comments from Member States, stakeholders and the outcome of the discussions at the EURL/NRL workshop, with a view to finalise the technical discussions and submit the draft Commission Implementing Regulation for an opinion at a next meeting of the Committee.

A.07 Feedback on discussions in recent meetings of the Working Groups on contaminants.

A.07.01 By means of Regulation (EU) 2021/1323 the **maximum level (ML) for cadmium in radishes** was lowered from 0.10 mg/kg to 0.020 mg/kg. Under the pesticides classification (Regulation (EC) No 396/2005), tiger nuts are included in the category "radishes". As Regulation (EC) No 1881/2006 follows the pesticides classification for vegetables, this means that the ML for cadmium for radishes of 0.020 mg/kg also applies to tiger nuts. The company 'Tigernuts' sent data, which show that tiger nuts are more prone to cadmium uptake than radishes and it provided scientific information, which shows that tiger nuts are a different type of plants, compared to

radishes. The provided data indicate that an increase of the ML from 0.020 to 0.10 mg/kg should be discussed. A proposal for such an amendment is currently under discussion in the Working Group on Industrial and Environmental Contaminants in Food.

By means of Regulation 2021/1323 the **MLs for cadmium in cultivated mushrooms** were lowered, mainly on the basis of data for common mushroom, Oyster mushroom and Shiitake mushrooms. The European Mushroom Growers Group (EMGG) collected data for cultivated mushrooms other than common mushroom (*Agaricus bisporus*), Shiitake or Oyster mushrooms. To these other cultivated mushrooms the same ML as for common mushrooms applies: 0.050 mg/kg. According to the data of the EMGG its seems that the concentrations in those other cultivated mushrooms are higher and that it might be appropriate to increase the ML for those mushrooms. Therefore a proposal is under discussion for an increase of the ML for cultivated mushrooms other than common mushroom, Oyster mushroom and Shiitake mushrooms on the basis of the occurrence data.

The Commission informed that a proposal for MLs of **nickel** in food is under discussion on the basis of the corresponding 2020 EFSA opinion.

A.07.02 Acrylamide, 3-MCPD esters and glycidyl esters

A questionnaire was sent to the Member States, to be answered by 30 September 2022, which enquired about:

As regards acrylamide, the review of the existing benchmark levels, the establishment of benchmark levels for foods for which no benchmark level are yet established and the establishment of maximum levels.

As regards 3-MCPD esters and glycidyl esters, the establishment of maximum levels in foods for which no maximum level was established yet.

An overview of the Member States that have replied was provided. Member States that had not yet submitted their reply to the questionnaire were requested to do so, as soon as possible. The answers to the questionnaire will be discussed in detail at the Working group meeting Industrial and Environmental Contaminants to take place on 21 November 2022. In addition, an analysis of recent occurrence data shall be made available to support the discussion on the appropriate maximum levels. The aim is to come to conclusions on the review of benchmark levels, setting of benchmark levels (for acrylamide) and the setting of maximum levels (acrylamide, glycidyl esters, 3-MCPD esters) by January 2023. A new stakeholder forum is foreseen at the end of January to inform all stakeholders about the outcome of these discussions.

A.07.03 The contamination incident in the Oder river

Extensive information on this contamination incident has been made available by the German (<u>https://www.bmuv.de/en/pressrelease/oder-fish-die-off-salt-discharges-</u> <u>caused-mass-proliferation-of-toxic-alga</u>) and Polish (<u>https://ios.edu.pl/wp-</u> <u>content/uploads/2022/10/Odra_briefing_ENG.pdf</u> authorities.

Starting on 26/27 July, dead fish was discovered in the Oder river by anglers. Since then, both in Poland and Germany over 200 tons of fish were found and removed from the river, along with several other species like mussels. Investigations have shown that the fish died from a combination of high salinity (*high level of chlorides and sulphates, due to industrial emissions*) and a massive proliferation of toxic brackish water alga

(*Prymnesium parvum*), adding to the stresses on the river Oder already arising through intense climate conditions.

Many analyses have been performed on the water from the Oder for heavy metals and for more than 1,200 potentially harmful chemicals, using non-targeted analysis. While the analysis identified many compounds in the Oder, none of these could have led to a mass die-off or resulted in levels of these compounds in food of fish origin potentially harmful for public health.

A.07.04: A.O.B. point

Belgium raised the issue of illegal use by a Polish feed manufacture of fatty acids with a technical purpose in the production of feed, mainly poultry feed (*RASF notification 2022-5755*). The Committee was informed that the Polish authorities have already taken many samples of these fatty acids and feeds produced with them in all involved feed manufacturing plants. The samples were tested for the presence of dioxins, PCBs, heavy metals and pesticides. At the same time, the feed from which the samples were taken was blocked. The analytical results so far do not indicate any non-compliance with EU maximum levels for dioxins, PCBs and heavy metals and with EU maximum residue levels for pesticides. Therefore, it can be concluded that this illegal use of fatty acids for a technical purpose for the production of animal feed did not have a negative impact on animal health or did not result in unacceptable levels of dioxins, PCBs, heavy metals and pesticides in the food of animal origin produced from the animals fed with the concerned feed.

B.01 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 and the Annex to Regulation (EU) No 231/2012 as regards the use of carbomer in food supplements.

The Commission presented the draft Commission Regulation authorising carbomer as a bulking agent and stabiliser in solid food supplements and as a thickener and stabiliser in liquid food supplements. The proposed uses of crosslinked polyacrylic acid polymers (carbomer) were assessed by EFSA which concluded that its use at the maximum level in liquid food supplement and at the typical use level reported by the applicant in solid food supplement is of no safety concern. It is therefore appropriate to authorise carbomer as a food additive in food supplements.

Vote taken: Favourable opinion.

B.02 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 and the Annex to Regulation (EU) No 231/2012 as regards the use of glucosylated steviol glycosides as sweetener.

The Commission presented the draft Commission Regulation authorising glucosylated steviol glycosides as a sweetener. The proposed uses of glucosylated steviol glycosides were assessed by EFSA which concluded that its use in the same conditions as the group of steviol glycosides (E960a-E960c) does not raise a safety concern. It is therefore appropriate to authorise glucosylated steviol glycosides as a sweetener and to rename the group of steviol glycosides as (E 960a-E960d).

Vote taken: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards the inclusion of 2-hydroxy-4methoxybenzaldehyde in the Union list of flavourings.

The Commission presented the draft Commission Regulation for the inclusion of 2hydroxy-4-methoxybenzaldehyde in the Union list of flavourings. The substance was assessed by EFSA. EFSA concluded that there is no safety concern at the estimated level of dietary exposure as far as the flavouring is isolated from the plant *Periploca Sepium* in order not to contain 1-methyl-2-pyrrolidone. It is therefore appropriate to include 2-hydroxy-4-methoxybenzaldehyde in the Union List of flavourings.

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Directive (EU) amending Directive 2009/32/EC of the European Parliament and of the Council as regards 2-methyloxolane.

The Commission presented the draft Commission Directive authorising 2methyloxolane as a new extraction solvent for the extraction processes in the production or fractionation of fats, oils or cocoa butter, in the preparation of defatted protein products, defatted flours, and in the preparation of defatted cereal germs and flavourings from natural flavouring materials. The proposed uses were assessed by EFSA, which in January 2022 adopted its opinion establishing a tolerable daily intake ('TDI') of 1 mg/kg bw per day and concluding that the extraction solvent 2methyloxolane does not raise a safety concern when used as intended and when respecting the proposed maximum residue limits (MRLs). It is therefore appropriate to authorise 2-methyloxolane as a new extraction solvent. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than two years after the date of entry into force of this Directive.

Vote taken: Favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) authorising the placing on the market of the frozen, paste, dried and powder forms of *Alphitobius diaperinus* larvae (lesser mealworm) as a novel food and amending Implementing Regulation (EU) 2017/2470.

The Commission presented to the Committee the draft act authorising the placing on the market of the frozen, paste, dried and powder forms of *Alphitobius diaperinus* larvae (lesser mealworm) as a novel food. The measure, which is underpinned by a favourable EFSA opinion, authorises the novel food in a number of food products for the general population, and in food supplements for the adult population.

Vote taken: Favourable opinion.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) authorising the placing on the market of the freeze-dried powder form of *Antrodia camphorata* mycelia as a novel food and amending Commission Implementing Regulation (EU) 2017/2470.

The Commission presented to the Committee the draft act authorising the placing on the market of the freeze-dried powder form of *Antrodia camphorata* mycelia as a novel

food. The measure, which is underpinned by a favourable EFSA opinion, authorises the novel food in food supplements for individuals aged 14 years and above.

Vote taken: Favourable opinion.

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) correcting Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods, Implementing Regulation (EU) 2018/1648 authorising the placing on the market of xylo-oligosaccharides as a novel food, Implementing Regulation (EU) 2019/1686 authorising the extension of use of bovine milk basic whey protein isolate as a novel food, and Implementing Regulation (EU) 2021/96 authorising the placing on the market of 3'-sialyllactose sodium salt as a novel food.

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 four errors in the Union list of novel foods. The first error relates to the novel food 'bovine milk basic whey protein isolate'. In Table 1 of the Annex to Implementing Regulation (EU) 2019/1686, in which the lines separating the specified food categories and the maximum authorised levels were erroneously omitted, it was unclear what food category corresponds to what authorised use. The second error refers to the novel food '3'-Sialyllactose sodium salt (microbial source)'. The maximum levels indicated for the food category 'Flavoured fermented milk-based products including heat-treated products' were erroneously added to the food category 'Unflavoured fermented milkbased products', and vice versa. The third error refers to the novel food 'Galactooligosaccharide' (GOS). The microbial source 'Bacillus circulans' of the enzyme 'βgalactosidase' used for the production of the GOS was erroneously added to the specifications. The last error was related to the novel food 'Xylo-oligosaccharide'. The specifications of the syrup form of 'Xylo-oligosaccharide' erroneously did not contain the parameter 'dry material' in the corresponding column.

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 vitamin D2 mushroom powder as a novel food and amending Commission Implementing Regulation (EU) 2017/2470.

The Commission presented to the Committee the draft proposal authorising the placing on the market of vitamin D2 mushroom powder as a novel food for use in a number of foods. The decision on the authorisation by means of a Commission Implementing Regulation is based on a positive EFSA opinion, published on 10 June 2022, and is intended to amend the Union list.

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 bovine milk osteopontin as a novel food and amending Commission Implementing Regulation (EU) 2017/2470.

The Commission did not present to the Committee the draft act authorising the placing on the market of bovine milk osteopontin as a novel food, as there was a need to discuss it further in the Working Group on novel foods. **Vote Postponed**

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 partially defatted whole *Acheta domesticus* (house cricket) powder as a novel food and amending Commission Implementing Regulation (EU) 2017/2470.

The Commission presented to the Committee the draft proposal Commission Implementing Regulation (EU) authorising the placing on the market of partially defatted whole Acheta domesticus (house cricket) powder as a novel food. The measure, which is underpinned by a favourable EFSA opinion, authorises the use of partially defatted whole Acheta domesticus (house cricket) powder in a number of foods intended for the general population.

Vote taken: Favourable opinion.

B.11 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) authorising the placing on the market of betalactoglobulin as a novel food and amending Commission Implementing Regulation (EU) 2017/2470.

The Commission presented to the Committee the draft proposal Commission Implementing Regulation (EU) authorising the placing on the market of betalactoglobulin as a novel food. The measure which is underpinned by a favourable EFSA opinion, authorises the use of beta-lactoglobulin in a number of foods intended for the general population.

Vote taken: Favourable opinion.

B.12 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) authorising the placing on the market of pea and rice protein fermented by *Lentinula edodes* (Shiitake mushroom) mycelia as a novel food and amending Commission Implementing Regulation (EU) 2017/2470.

The Commission presented to the Committee the draft proposal Commission Implementing Regulation (EU) authorising the placing on the market of pea and rice protein fermented by *Lentinula edodes* (Shiitake mushroom) mycelia as a novel food. The measure which is underpinned by a favourable EFSA opinion, authorises the use of pea and rice protein fermented by Lentinula edodes (Shiitake mushroom) mycelia in a number of foods intended for the general population.

Vote taken: Favourable opinion.

B.13 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) authorising the placing on the market of Lacto-*N*tetraose 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 proposal Commission Implementing Regulation (EU) authorising the placing on the market of Lacto-N-tetraose produced by derivative strains of *Escherichia coli* BL21 DE3 as a novel food. The measure which is underpinned by a favourable EFSA opinion, authorises the use of Lacto-N-tetraose produced by derivative strains of *Escherichia coli* BL21 DE3 in a

number of foods intended for the general population, in infant and follow on formula, in foods for special medical purposes for infants and in foods for special medical purposes excluding foods for infants and young children, and in food supplements intended for the general population excluding the use in food supplements for infants and young children.

Vote taken: Favourable opinion.

B.14 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) authorising the placing on the market of 3-Fucosyllactose produced by a derivative strain 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 proposal Commission Implementing Regulation (EU) authorising the placing on the market of 3-Fucosyllactose produced by a derivative strain of *Escherichia coli* BL21 DE3 produced by derivative strains of *Escherichia coli* BL21 DE3 as a novel food. The measure which is underpinned by a favourable EFSA opinion, authorises the use of 3-Fucosyllactose produced by a derivative strain of *Escherichia coli* BL21 DE3 in a number of foods intended for the general population, in infant and follow on formula, in foods for special medical purposes for infants and in foods for special medical purposes excluding foods for infants and young children and in food supplements intended for the general population excluding the use in food supplements for infants and young children.

Vote taken: Favourable opinion.

B.15 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) authorising the placing on the market of 3'-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 proposal Commission Implementing Regulation (EU) authorising the placing on the market of 3'-Sialyllactose sodium salt produced by derivative strains of *Escherichia coli* BL21 DE3 produced by derivative strains of *Escherichia coli* BL21 DE3 as a novel food. The measure which is underpinned by a favourable EFSA opinion, authorises the use 3'-Sialyllactose sodium salt produced by derivative strains of *Escherichia coli* BL21 DE3 in a number of foods intended for the general population, in infant and follow on formula, in foods for special medical purposes for infants and in foods for special medical purposes excluding foods for infants and young children and in food supplements intended for the general population excluding the use in food supplements for infants and young children.

Vote taken: Favourable opinion.

B.16 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Regulation (EC) No 1881/2006 as regards maximum levels of arsenic in certain foods.

The Commission presented the draft proposal and explained its contents. The Regulation would lower the maximum level (ML) for non-parboiled milled rice and establish new maximum levels for inorganic arsenic in rice flour, rice-based drinks, food for infants and young children, fruit juices and nectars and a new maximum level

for total arsenic in salt. Originally this proposal also included new MLs for arsenic in fish and other seafood. However additional comments and figures from third countries and stakeholders show that the MLs for certain fish, crustacean and bivalve mollusc species would require further fine-tuning. As data are currently lacking for certain of those species, the MLs for fish and other seafood have been removed from this proposal and will be dealt with under a separate proposal, in order to allow Member States, stakeholders and third countries to submit additional data to the Commission. Occurrence data for inorganic arsenic in fish and other seafood can be sent by stakeholders, third countries and Member States to the Commission by 31 December 2022. The concentrations of inorganic arsenic in the individual samples should be submitted, instead of aggregated data. A Member State enquired on the way the transitional measure, which foresees that 'foodstuffs that were lawfully placed on the market before the entry into force may remain on the market until their date of minimum durability or use-by date', would be applied to salt, which has no such date. The Commission explained that salt which was lawfully placed on the market before the entry into force of the measure, may also remain on the market.

Vote taken: Favourable opinion.

B.17 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) amending Commission Regulation (EU) 2019/1871 as regards the application of reference points for action for nitrofurans and their metabolites.

The Commission presented the draft Commission Regulation (EU) amending Commission Regulation (EU) 2019/1871 as regards the application of reference points for action for nitrofurans and their metabolites. Regulation (EU) 2019/1871 on reference points for action for non-allowed pharmacologically active substances present in food of animal origin establishes reference points for action (RPAs) for certain prohibited substances, which will become applicable as from 28 November 2022. From that date, lower values of RPAs (than currently applicable) shall apply to all food of animal origin. The illegal treatment of food by nitrofurans and their metabolites results in findings of several metabolites together in one sample. Based on the available information, the presence of nitrofuran metabolite semicarbazide (SEM) in certain processed products (gelatine, collagen hydrolysate, hydrolysed cartilage products, spray dried blood products, whey and milk protein concentrates, caseinates and milk powder (not including infant formulae and follow-on formulae)) may arise during processing from naturally occurring compounds and is not related to an illegal treatment by nitrofurans. It is therefore appropriate to exempt the application of the RPA to findings where only semicarbazide is present in those processed products. If other nitrofuran metabolites would be present in the sample, together with semicarbazide, the exemption is not applicable. In order to enable the Commission to establish in the near future specific regulatory measures as regards the presence of SEM in the products for which the exemption is foreseen, food business operators and other interested parties should provide by 1 March 2024 necessary data and information on investigations on the parameters and factors in the processing steps resulting in the formation of SEM during processing in those processed products. Food business operators should also take measures to reduce the presence of SEM in these products at levels as low as reasonably achievable and report on these measures taken. In the absence of those data and information, the exemption shall be deleted. The Regulation shall apply from 28 November 2022, the date from which the lower RPAs are applicable. A Member State abstained because of the late addition of certain processed products to the exemption and time was too short to perform a risk assessment at national level for these products.

Vote taken: Favourable opinion.

B.18 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006.

The Commission presented the draft Commission Regulation (EU) on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006. Commission Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in food has been amended many times. In order to improve the readability and clarity of this Regulation, this Regulation replaces Regulation (EC) No 1881/2006, including all subsequent amendments. The proposal also contains previously agreed or endorsed clarifications that were not yet introduced into Commission Regulation (EC) No 1881/2006 due to the expected and upcoming replacement of the said Regulation. Member States will have the opportunity to send their linguistic comments before adoption of the draft Regulation by the Commission.

Vote taken: Favourable opinion.

B.19 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Regulation (EC) No 333/2007 as regards the methods for sampling and analysis for the control of the levels of trace elements and processing contaminants in foodstuffs.

The Commission presented the proposal and explained its contents. A Member State commented on the LOQ requirements for mercury and suggested to align these with those for arsenic. The Commission explained that the scope of the current proposal concerns methods for arsenic only. However, the need for possible changes in the method requirements for other heavy metals can be discussed in the Working Group on Industrial and Environmental Contaminants in Food.

Vote taken: Favourable opinion.

B.20 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) Amending Annex I to Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food, as regards changes to substance authorisations and addition of new substances.

The proposal authorises five new substances for the manufacture of plastic materials and articles on the basis of new EFSA opinions, lowers the limits for four phthalates, and amends two other substance authorisations. It also revokes authorisations for salicylic acid and untreated wood flour and fibres. The Commission shortly explained the text and opened the floor for questions. Answering to one of them, it commented that, in case there would be substantial questions regarding an EFSA opinion, it is important to clarify possible issues with the Authority at an early stage, to facilitate the work of risk managers later on.

Vote taken: Favourable opinion.