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Standing Committee on Plants, Animals, Food and Feed
Section *Novel Food and Toxicological Safety of the Food Chain*
21 April 2022

CIRCABC Link: *https://circabc.europa.eu/w/browse/39b13c55-0125-4bc0-886a-4dc8a1d6cdf2*

SUMMARY REPORT

A.01 Mineral oil hydrocarbons in food: follow-up to the December 2021 Foodwatch report.

At the February SC PAFF meeting, the follow-up to the 2021 Foodwatch report on Mineral Oil Hydrocarbons (MOHs) in food was discussed. Some Member States requested to define harmonised limits of quantification (LOQs) for different food groups, in order to have the same cut-off values for enforcement throughout the EU. Taking into account the performance requirements for LOQs in Table II of the JRC Guidance[1] a joint statement by the Member States on the presence of Mineral Oil Aromatic Hydrocarbons (MOAH) in food was drafted.

A Member State commented that the principle of determining LOQs per C-fraction should no longer be maintained, as there is no link between certain toxicological effects and specific C-fractions. The Commission confirmed that it is indeed the intention to amend the JRC Guidance accordingly. However the update of the Guidance will be done after the conclusions of the updated EFSA risk assessment will be made available, so that possible new EFSA reporting recommendations can be taken into account. The Member State proposed to carry out an integration of the total MOAH fraction, without the consideration of individual fraction limits, and to apply the maximum LOQs from the JRC Guidance as limits for the total MOAH fraction. It was agreed to amend the statement accordingly. A Member State enquired whether the new statement would replace the statement of the SC PAFF of 23 June 2020 on the presence of mineral oil aromatic hydrocarbons (MOAH) in infant formula and follow-on formula. The Commission confirmed that this is the case and clarified it in the statement. The Commission informed the Member States on stakeholder comments in favour of waiting for the updated EFSA risk assessment before taking further risk management measures. As the finalisation of the EFSA opinion and the establishment of Maximum Levels will take time, and in view of the toxicity of certain fractions of MOAH, it was considered appropriate to move forward with the statement already. A Member State expressed its preference for maximum levels, but it considered the statement as a good temporary solution. A Member Sate state indicated that all controls confirming the quantified presence of MOAH should lead to withdrawals and not only official controls.

[1] "Guidance on sampling methods, on the performance criteria for the analytical methods and on the reporting of the analytical results" (https://publications.jrc.ec.europa.eu/repository/handle/JRC115694).

The Commission explained that the statement harmonises follow-up by the Member States on the basis of official controls, but that, if a food business operators identifies the presence of MOAH in food, it also has to take the necessary follow-up actions in accordance with its obligations under Articles 14 and 19 of Regulation (EC) No 178/2002. A Member State enquired about the time when the statement would become applicable. The Commission explained that it will be applicable as from the moment the minutes of the SC PAFF meeting of 21 April 2022 are published.

The Committee agreed to the following statement:

Joint statement of the Member States regarding the presence of Mineral Oil Aromatic Hydrocarbons (MOAH) in food, including food for infants and young children[2]

Following recent findings of the presence of mineral oil aromatic hydrocarbons (MOAH) in certain foods, the Commission services requested the relevant competent authorities and food business operators to follow-up on the findings and to sample and to analyse the products (stock cubes and other products) which have been found to contain MOAH, to perform investigations on the source of contamination (ingredients, food additives, food contact materials, lubricants and others) and to report on the outcome of the investigations. It is appropriate that Member States and food business operators perform controls on the presence of MOAH in microcrystalline wax (petroleum wax, synthetic paraffin) and its potential migration to food, to confirm whether the use of microcrystalline wax in food contact materials is a source of the contamination of food by MOAH and take, if necessary, measures to prevent the occurrence of MOAH in food. It should also be checked whether microcrystalline wax, used in food contact materials is claimed to be E905 (microcrystalline wax authorised for specific food additive uses) and, if this is the case, whether it complies with the specifications of E905, in particular as regards the presence of benzo[a]pyrene.

For the sampling and analysis, the JRC has published a "Guidance on sampling *methods, on the performance criteria for the analytical methods and on the reporting of the analytical results (https://publications.jrc.ec.europa.eu/repository/handle/JRC115694).*

If the quantified presence of MOAH, which are possible genotoxic carcinogens, in food including food for infants and young children is confirmed by an official control, the products concerned should be withdrawn and, if necessary, recalled from the market on the basis of Article 14 of the General Food Law (Regulation (EC) No 178/2002), to ensure a high level of human health protection. In this regard the Member States also stress the responsibilities of food business operators in accordance with Article 19 of the General Food Law.

In order to ensure a uniform enforcement approach throughout the EU, the Member States agreed to withdraw and, if necessary, to recall products from the market, when the sum of the concentrations of MOAH in food are at or above the following maximum LOQs:

- *0.5 mg/kg for dry foods with a low fat/oil content (≤4% fat/oil)*
- *1 mg/kg for foods with a higher fat/oil content (> 4% fat/oil)*

[2] This statement replaces the statement of the SC PAFF of 23 June 2020 on Presence of mineral oil aromatic hydrocarbons (MOAH) in infant formula and follow-on formula – conclusion on harmonised risk management measures.

- *2 mg/kg for fats/ oils*

Analysis and sampling should be done according to the provisions of Regulation (EC) No 333/2007.

A.02 EFSA 2020 Report on the results of 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, EFSA informed on a new interactive data visualisation tool that shows the results in more details. The Commission informed Member States that the report is now published on the DG SANTE website.

A.03 Discussion and endorsement of the guidance on the implementation of the rules and practical arrangements for the performance of the official controls as regards contaminants in food.

The Commission presented to the Committee the guidance document regarding the performance of official controls on contaminants in food according to two Commission Regulations. Guidance is provided on: sampling and analysis, control frequencies, submission of the control plans, transmission of data and the list of legislation covering the measures on contaminants. The guidance document has been subject to extensive discussions within various working groups on contaminants. The Committee endorsed the guidance document with the changes agreed at the meeting. It is foreseen to publish the guidance document on the DG SANTE website.

A.04 Update on several topics related to contaminants in food.

The Committee was informed on:

- the progress and next steps on the draft Commission Implementing Regulation (EU) laying down the methods of sampling and analysis for the control of the levels of mycotoxins in foodstuffs and repealing Regulation (EC) No 401/2006
- the progress and next steps on the draft Commission Implementing Regulation (EU) laying down the methods of sampling and analysis for the control of the levels of plant toxins in food and repealing Regulation (EU) 2015/705
- the next steps as regards the regulation of 3-MCPD-esters and glycidyl esters in foods not yet directly regulated in Regulation (EC) No 1881/2006
- the recent publication of:

  Commission Recommendation (EU) 2022/495 of 25 March 2022 on monitoring the presence of furan and alkylfurans in food

  Commission Recommendation (EU) 2022/553 of 5 April 2022 on monitoring the presence of Alternaria toxins in food

  Commission Recommendation (EU) 2022/561 of 6 April 2022 on monitoring the presence of glycoalkaloids in potatoes and potato-derived products
- the importance of checking the language versions of the draft Regulations amending Regulation (EC) 1881/2006 setting maximum levels in food of delta-9-tetrahydrocannabinol, ochratoxin A and hydrocyanic acid.

- the comments received from the European Herb Growers Association (EUROPAM) in relation with the entry into application of the maximum levels for pyrrolizidine alkaloids on 1 July 2022.
- the need to refer to tapioca flour in addition to cassava flour in the draft Regulation establishing maximum levels for hydrocyanic acid as it concern different products.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) authorising the placing on the market of hydrogenated curcuminoids (tetrahydrocurcuminoids) from turmeric (Curcuma longa L.) as a novel food and amending Implementing Regulation (EU) 2017/2470.

The Commission presented to the Committee the draft Implementing Regulation authorising the placing on the market of hydrogenated curcuminoids (tetrahydrocurcuminoids) from turmeric (Curcuma longa L.) as a novel food. The measure which is underpinned by an EFSA opinion, authorizes the use of hydrogenated curcuminoids (tetrahydrocurcuminoids) from turmeric (Curcuma longa L.) in food supplements intended for the adult population and excluding pregnant and lactating women. A Member State abstained because of the proposed additional specific labelling requirement in the Annex "*b) they should not be consumed if other food supplements containing curcumin and/or curcuminoids are consumed on the same day*". That Member State does not see reasons for introducing a specific label requirement for tetrahydrocurcuminoids, as this approach would not be consistent with the labelling of food supplements in general; the corresponding risk of exceeding the ADI in the case of simultaneous use of several food supplements with the same substance is also present among non-novel food supplements without requiring a corresponding warning.

Vote taken by written procedure: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) authorising the placing on the market of kernels from Jatropha curca L. as a novel food and amending Implementing Regulation (EU) 2017/2470.

The Commission presented to the Committee the draft Implementing Regulation authorising the placing on the market of kernels from the edible variety of *Jatropha curca* L. as a novel food. The measure, which is underpinned by an EFSA opinion, authorizes the use of kernels from the edible variety of *Jatropha curca* L. as such or as processed nuts (or candied or sugar preserved), as a snack, and as an ingredient in cereal bars, in breakfast cereals, and in dried fruits.

Vote taken by written procedure: Favourable opinion.

B.03 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, the specific labelling requirements and specifications of the novel food Calanus finmarchicus oil.

The Commission presented to the Committee the draft Implementing Regulation amending Commission Implementing Regulation (EU) 2017/2470 as regards the conditions of use, the specific labelling requirements and specifications of the novel food *Calanus finmarchicus* oil. The measure authorizes an increased maximum level of

up to 0,25 % of astaxanthin esters contained in *Calanus finmarchicus* oil for persons older than fourteen years of age, in addition to the currently authorised maximum level of < 0,1 % of astaxanthin esters in *Calanus finmarchicus* oil for the general population. Furthermore, for food supplements containing the currently authorised level of < 0,1 % astaxanthin esters that are intended for the general population, the measure reduces the currently authorised use levels of the *Calanus finmarchicus* oil from 2,3 g/day to 1,0 g/day and excludes infants and young children from its use. Finally, the measure also lays down additional labelling requirement in order to prevent concomitant consumption of astaxanthin food supplements. A Member State abstained because of this proposed additional specific labelling requirement. That Member State does not see reasons for introducing a specific label requirement for tetrahydrocurcuminoids, as this approach would not be consistent with the labelling of food supplements in general; the corresponding risk of exceeding the ADI in the case of simultaneous use of several food supplements with the same substance is also present among non-novel food supplements without requiring a corresponding warning.

Vote taken by written procedure: 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 and the specifications of the novel food nicotinamide riboside chloride.

The Commission presented to the Committee the draft Implementing Regulation authorising the amendment of the conditions of use and the specifications of the novel food nicotinamide riboside chloride. The measure, which is underpinned by an EFSA opinion, authorizes the extension of use of nicotinamide riboside chloride to foods for special medical purposes, total diet replacement for weight control and meal replacements, all of those categories intended for the adult population, excluding pregnant and lactating women. The measure also amends the specification of the novel food to include maximum levels for heavy metals applicable to the new uses.

Vote taken by written procedure: Favourable opinion.

B.05 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 ascorbic acid and its salts (E 300-302) in Tuna.

The Commission presented the draft Commission Regulation amending the conditions of use of ascorbic acid and its salts (E 300-302) in Tuna. Those food additives are currently authorised in category 09.1.1 '*unprocessed fish'* and category 09.2 '*Processed fish and fishery products including molluscs and crustaceans*', at *quantum satis*. Following official controls, competent authorities regularly report cases where thawed tuna loins are found to contain the food additives in amounts higher than those considered by those competent authorities as necessary to achieve the typical antioxidant effect on fresh tuna. To ensure legal certainty, it is therefore appropriate to set maximum levels for the use of ascorbic acid (E 300), sodium ascorbate (E 301) and calcium ascorbate (E302) which apply only for tuna in food categories 09.1.1 and 09.2 in Part E of Annex II to Regulation (EC) No 1333/2008.

Vote taken by written procedure: Favourable opinion.

B.06 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 certain flavouring substances.

The Commission presented the draft Commission Regulation removing restrictions and footnotes for certain flavourings listed in Annex I to Regulation (EC) No 1334/2008. For these flavourings, due to a lack of data, the safety assessment was not completed when the Union list was established by Regulation (EU) No 872/2012. Subsequently, the Commission limited their uses by Regulation (EU) 2016/1244 pending the full evaluation by EFSA. Following the submission of the data by the applicants and the completion of the evaluations by EFSA, where EFSA concluded that there is no safety concern for these flavourings, the Commission proposed to amend Annex I, part A, to Regulation (EC) No 1334/2008 by removing the relevant restrictions and footnotes. One Member State expressed a concern regarding the safety of one substance for which the threshold of concern is reached following the mTAMDI exposure calculation. This concern was shared by two other Member States. No other comments were raised.

Vote taken by written procedure: Favourable opinion.

B.07 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 removal from the Union list of certain flavouring substances.

The Commission presented the draft Commission Regulation that removes some flavouring substances from the Union list. For these flavourings, due to lack of data, the safety assessment was not completed when the Union list was established by Regulation (EU) No 872/2012. Consequently, EFSA started evaluating those substances by requesting from the applicants additional scientific data. However, at some point of the process, the operators responsible for placing those substances on the market did not submit the required data and informed that they would not support those substances anymore. Therefore, the Commission proposed to remove those flavouring substances from the Union List and amend Regulation (EC) No 1334/2008 accordingly.

Vote taken by written procedure: Favourable opinion.

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation on uniform practical arrangements for the performance of official controls as regards contaminants in food, on specific additional content of multi-annual national control plans and specific additional arrangements for their preparation.

The Commission presented to the Committee the draft Commission Implementing Regulation on uniform practical arrangements and specific additional content of multi-annual national control plan for official controls of contaminants in food. After the repeal of Council Directive 96/23/EC (*on measures to monitor certain substances and residues thereof in live animals and animal products*), it is necessary to include the requirements for controls of organochlorine compounds, chemical elements and mycotoxins in food of animal origin in a new regulation on control plans for contaminants (*based on the Official Control Regulation*). The scope of these control plans is extended to all contaminants and also to food of non-animal origin. The draft lays down the annual uniform minimum frequencies of official controls on the presence

of contaminants in food and specific arrangements and specific content for the Member States' multi-annual national control plans as regards contaminants in food.

Vote taken by written procedure: Favourable opinion.

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) amending Regulation (EC) No 1881/2006 as regards maximum levels of dioxins and PCBs in certain foodstuffs.

EFSA recommended in its scientific opinion to re-evaluate the current WHO2005-TEFs (Toxic Equivalence Factors). The World Health Organisation (WHO) is currently performing a review of the WHO2005-TEF values, which is expected to be completed by the end of 2023.

Pending the completion of that review, and in order to provide for a high level of human health protection, the draft Regulation establishes maximum levels for dioxins and dioxin-like PCBs for foodstuffs not yet covered by EU legislation and for which in the meantime occurrence data have been made available in the EFSA database. This concerns food products such as meat and meat products from caprine animals, horse, rabbit, wild boar, wild game birds and venison and liver of caprine animals, horse and wild game birds, and extends the existing maximum level for hen eggs to all poultry eggs with the exception of goose eggs. In addition, taking into account the available occurrence data and the importance to ensure a high level of human health protection, in particular for vulnerable groups of the population, the maximum levels for dioxins and the sum of dioxins and dioxin-like PCBs in milk and dairy products is lowered.

Furthermore, given that not only muscle meat from appendages of crabs and crab-like crustaceans is consumed, but also muscle meat from the abdomen of such crustaceans, in particular mitten crab, it is appropriate that the maximum levels also apply to the muscle meat of the abdomen of these crustaceans. Following a comment that the muscle meat might be rather in the cephalothorax than in the abdomen, it was agreed to have a closer look into that question at the occasion of the recast of Regulation (EC) No 1881/2006, currently under discussion.

Vote taken by written procedure: Favourable opinion.