EUROPEAN COMMISSION

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 2024

CIRCABC Link: *https://circabc.europa.eu/ui/group/55b2edd3-069e-40fd-ad4a-8b163f54ff1f/library/2ee4e1aa-7090-44e3-948e-7dc9382714d9?p=1&n=10&sort=name_ASC*

SUMMARY REPORT

A.01 Information on exemption in application of RPA for semicarbazide in certain processed products (Commission Regulation (EU) 2019/1871)

The current exemption for the application of reference points for action (RPA) for semicarbazide (SEM) covers gelatine, collagen hydrolysate, hydrolysed cartilage products, spray dried blood products, whey and milk protein concentrates, caseinates and milk powder (excluding infant formulae and follow-on formulae) based on the evidence that SEM can occur at levels above the RPA as a consequence of processing. The RPA of 0,5 µg/kg for SEM shall only be applied in these products, when the illegal use of nitrofurazone or SEM has been established, i.e. at least one of the other nitrofuran metabolites has been detected. At the meeting of the Working Group on residues of veterinary medicinal products on 13 December 2023, the request from a food business operator for the exemption of collagen in application of the RPA was presented. The FBO provided evidence that, following the requirements for production of collagen as laid down in Regulation (EC) No 853/2004, a natural formation of SEM can be observed. Member States agreed that the exemption in Commission Regulation (EU) 2019/1871 should also be applied to collagen. Since the final technical discussion on the measures as regards the exemption in application of RPA for SEM in certain processed products is planned to be held in March 2024, the appropriate amendment in Regulation (EU) 2019/1871 will be adopted and in application several months after this discussion. Therefore, when enforcing the legislation, Member States are advised to already apply the exemption also to collagen, pending the adoption and entry into application of the amendment to Regulation (EU) 2019/1871 which will legally formalise this exemption.

A.02 Draft Commission Recommendation on the monitoring of nickel in food (for endorsement)

The Commission presented the draft and explained its contents, in relation to points B.11 and B.12 of the agenda. The Recommendation was endorsed by the Committee.

A.03 Update and exchange of views on different topics related to contaminants in food

Feedback was provided on the discussions that has taken place in meetings of the Working Group (WG) on contaminants since the previous meeting of the Committee.

Agricultural contaminants – meetings of 21 December 2023 and 14 February 2024

- Discussions were finalised on the provisions on ergot sclerotia and ergot alkaloids (*see point B.10*) and on sampling provisions for the control of mycotoxins and plant toxins in dried herbs, herbal infusions (dried product), teas (dried product) and powdered spices (*see point B.13*) and on changes to certain provisions in Regulation (EU) 2023/915 as regards agricultural contaminants (*see point B.14*).
- An approach was discussed for a draft Commission Regulation providing rules to be applied by business operators as regards the sampling and analysis when performing obligatory auto-controls on the presence of mycotoxins and plant toxins; a targeted stakeholder consultation has been launched on the approach.
- Conclusion on maximum levels for aflatoxin B1 of 5 µg/kg and aflatoxin total of 10 µg/kg in tiger nuts.
- Discussion on a maximum level for Δ-9 THC in hemp leaves for infusion.
- A draft Commission recommendation on quinolizidine alkaloids in food was discussed.
- The maximum level for deoxynivalenol in wheat bran not placed on the market for the final consumer will be reconsidered.
- The exemption from different mycotoxin maximum levels for unprocessed maize to be processed by wet milling will continue to apply, but Member States are recommended to monitor the presence of mycotoxins in products of the wet milling process other than starch for human consumption and to report on any significant findings of mycotoxins in these products.
- The information provided by Türkiye as regards the maximum level for ochratoxin A in dried apricots and dried mulberries and for hydrocyanic acid in apricot kernels will be examined in detail in view of a possible future amendment to the Regulation.
- More information will be requested from the stakeholder organisations as regards the sorting and physical treatments applied for rice to reduce the aflatoxin contamination.

POPs in food - meeting of 11 December 2023

- An approach for the analysis of chlorinated paraffins in food (*and feed*) was agreed. The sum of polychlorinated alkanes (PCAs) C10-17 is to be analysed as a semi-quantitative screening against a threshold. If the threshold is exceeded, a more specific analysis is recommended. A monitoring recommendation will be prepared on this basis.

- The next steps to be taken in view of a comprehensive review of the EU legislation on dioxins and dioxin-like PCBs following the publication of the new WHO-TEF values for dioxins and dioxin-like PCBs have been presented.

- Discussions took place on possible amendments to the derogation for dioxins and dioxin-like PCBs in fish from the Baltic region as provided in Article 7(2) of Commission Regulation (EU) 2023/915. A conclusion was reached to change the length of wild caught Baltic herring from 17 cm to 19 cm in the derogation for Sweden and Finland and to provide a derogation for wild caught whitefish (*Coregonus* sp.*)* and products thereof originating in the lakes Vänern and Vättern for Sweden.

- Discussions have started on maximum levels for non-dioxin-like PCBs in meat and meat products of horse, rabbit, wild boar (*Sus scrofa)*, wild game birds, of *Cervidae* (e.g. venison), liver and derived products of wild game birds.

Industrial and Environmental contaminants – meeting of 14 December 2023

- Discussion on the establishment of maximum levels for 3-MCPD esters and glycidyl esters in cereal based foods for infants and young children (*including biscuits and rusks*) and baby food (*ready-to-eat meals for infants and young children*) were finalised in view of a targeted stakeholder consultation.
- Maximum levels were discussed for PAH in freekeh (roasted durum wheat).
- An update was provided on the ongoing discussions as regards:
    - acrylamide (*review of benchmark levels and establishment of maximum levels*)
    - the establishment of maximum levels of 3-MCPD esters and glydicyl esters in certain foods, and
    - regulatory measures on N-nitroamines in food

Mineral oil hydrocarbons

The Commission explained that, following the 2023 update by European Food Safety Authority of the risk assessment of mineral oil hydrocarbons (MOHs) in food, three proposals for its Regulatory follow-up are under discussion:

-A Regulation on maximum levels (MLs) for mineral oil aromatic hydrocarbons (MOAH) in food.

-A monitoring Recommendation for MOHs in food.

-A Regulation on the methods for the sampling and analysis of MOHs in food.

Currently MLs are proposed at levels of 0.5 to 2.0 mg/kg of MOAH in food, depending on the fat content of the products. MLs are proposed for all commodities, in which significant concentrations of MOAH can be found.

Under the monitoring Recommendation, Indicative Levels (ILs) are recommended at levels between 1.5 and 15 mg/kg of mineral oil saturated hydrocarbons (MOSH) in food. When the concentrations of MOSH would exceed these levels, it is recommended to carry out investigations towards the sources of the contamination and to apply the necessary mitigation measures. Nevertheless, the ILs should not be used as a threshold for removing products from the market.

These proposals were discussed with the Member States (MS) during the Working Group on Industrial and Environmental Contaminants in Food. Subsequently a

stakeholder forum was organised on 18 January 2024, to which also MS could participate.

At this forum:

-It appeared that some sectors made a lot of progress since the 2017 monitoring Recommendation on MOHs in food and the 2022 statement of the SC PAFF, while other sectors urgently need to take further action, in particular to investigate the sources of the contamination throughout their production chain;

-Comments were made as regards the achievability of the limits of quantification (LOQs) for certain complex products. It was requested to send further comments in writing, with information on the achievable LOQs. The European Reference Laboratory on Processing Contaminants in Food will be consulted and, where needed, this information will be taken into account for the further discussions;

-Several stakeholders raised issues about the difficulty to convince third country suppliers to take measures to avoid the presence of MOHs in their products. In order to help the EU food business operators (FBOs) with awareness raising, an information note was prepared and circulated. The EU FBOs can use this note to inform third country FBOs on the contamination of food with MOHs. Also for the 17th Codex Committee on Contaminants in Food a document will be prepared, so that the EU can bring the matter of MOHs in food to the attention of third country competent authorities;

-Certain sectors commented that the proposed MLs for certain commodities are not achievable, while Foodwatch insisted on MLs at the LOQs for all foods, without exception;

-In case stakeholders would consider that certain MLs are not achievable yet, they were requested to support these comments with information explaining:

Why these MLs cannot be achieved yet

Why part of the production cannot comply, while the majority does comply already

What are the sources of the contamination

Which mitigation measures are/ will be implemented

The timelines for achieving compliance with the ML

The raw occurrence data with information on the applied mitigation measures.

Stakeholders were requested to send these comments to the Commission by 27 February 2024. These comments will then be considered for the further discussions with the Member States on the regulatory proposals on MOHs in food.

Inorganic arsenic

A proposal with MLs for inorganic arsenic in fish and other seafood was discussed. In December 2023 a targeted stakeholder consultation was launched on the proposal with a deadline of 26 January 2024. The comments from stakeholders will be processed and taken into account for the further discussions on the proposal in the Working Group on Industrial and Environmental Contaminants in Food.

A.04 Feedback on the recent work of the PAFF Working Group on Food Contact Materials (FCM)

The FCM team provided feedback on the meeting of the FCM WG of the SC-PAFF that took place on 22 and 23 January. After a short discussion on the state of play of the legislation revision work, the amendments to Regulation (EU) No 10/2011, Regulation (EC) No 2023/2006 and Regulation (EU) 2022/1616 were discussed in detail, followed by a discussion on a new measure restricting the use of Bisphenol A in FCMs. A handout of the slides is available. Also the further preparation of the Authorisation decisions on mechanical PET recycling was discussed.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) amending Annex II and Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the food additives tartaric acid (L(+)-) (E 334), sodium tartrates (E 335), potassium tartrates (E 336), potassium sodium tartrate (E 337) and calcium tartrate (E 354)

The Commission presented the draft Commission Regulation amending the conditions of use of tartaric acid-tartrates (E 334-337 and E 354). These food additives are currently authorised for use at *quantum satis* and included in Group I, in Annex II, Part C of Regulation (EC) No 1333/2008, which covers food additives other than colours and sweeteners with an '*acceptable daily intake not specified'* or for which the most recent risk assessment concluded that '*there is no need for a numerical acceptable daily intake'*. In addition, tartaric acid (L(+)-) (E 334), sodium tartrates (E 335), potassium tartrates (E 336), sodium potassium tartrate (E 337) and calcium tartrate (E 354) are authorised for use in specific food categories with a numerical maximum use level or at *quantum satis*. The European Food Safety Authority (EFSA) re-evaluated these food additives in 2020 and established a group acceptable daily intake (ADI) of 240 mg/kg bw per day, expressed as tartaric acid, for tartaric acid-tartrates (E 334 - 337 and E 354). Following the EFSA re-evaluation, it is appropriate to remove these food additives from Group I, create a new group for them, review their conditions of use and establish numerical maximum use levels. A transitional period will be granted to allow food business operators to adapt to the new more stringent conditions of use.

Vote taken: Favourable opinion.

B.02 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 galacto-oligosaccharide

The Commission presented to the Committee the draft act authorising the changes in the specifications of the already authorised novel food galacto-oligosaccharide.

Vote taken: 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 specifications of the novel food astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae

The Commission presented to the Committee the draft act authorising the changes in the specifications of the already authorised novel food astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae. The decision on authorising these changes is based on a positive EFSA opinion.

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 lactitol

The Commission presented to the Committee the draft act authorising the changes in conditions of use of the already authorised novel food lactitol.

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 3′-Sialyllactose sodium salt produced by a derivative strain of Escherichia coli W (ATCC 9637) 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 a 3′-Sialyllactose sodium salt produced by a derivative strain of Escherichia coli W (ATCC 9637) as a novel food. The novel food is to be used in the same foods as the currently authorised 3′-Sialyllactose sodium salt which is produced by different *E. coli* derivatives.

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 beta-glucan from *Euglena gracilis* microalgae 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 beta-glucan from *Euglena gracilis* microalgae as a novel food on the basis of a positive EFSA opinion. Beta-glucan from *Euglena gracilis* microalgae is to be used in cereal bars, total diet replacement for weight control as defined in Regulation (EU) No 609/2013 and food supplements as defined in Directive 2002/46/EC, excluding food supplements for infants and young children.

Vote taken: Favourable opinion.

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) authorising the placing on the market of water lentil protein concentrate from a mixture of *Lemna gibba* and *Lemna minor* as a novel food and amending Implementing Regulation (EU) 2017/2470

The Commission presented the draft act authorising the placing on the market of water lentil protein concentrate from a mixture of *Lemna gibba* and *Lemna minor* as a novel food on the basis of a positive EFSA opinion. Water lentil protein concentrate from a mixture of *Lemna gibba* and *Lemna minor* is to be used in cereal bars, prepacked bread and rolls, powdered drink mixes and noodles for the general population and food supplements as defined in Directive 2002/46/EC for the adult population.

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 monosodium salt of L-5-methyltetrahydrofolic acid as a novel food and amending Implementing Regulation (EU) 2017/2470

The Commission presented the draft act authorising the placing on the market of a monosodium salt of L-5-methyltetrahydrofolic acid as a novel food on the basis of a positive EFSA opinion. The monosodium salt of L-5-methyltetrahydrofolic acid is to be used in food supplements as defined in Directive 2002/46/EC, excluding food supplements for infants and young children, food intended for infants and young children (*infant formula and follow-on formula; processed cereal-based food and baby food*), food for special medical purposes and total diet replacement for weight control as defined in Regulation (EU) No 609/2013, and fortified foods as defined in Regulation (EC) No 1925/2006.

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 calcidiol monohydrate as a novel food and amending Implementing Regulation (EU) 2017/2470

The Commission presented the draft act authorising the placing on the market of calcidiol monohydrate as a novel food on the basis of a positive EFSA opinion. Calcidiol monohydrate is to be used in food supplements as defined in Directive 2002/46/EC, excluding food supplements for infants and young children.

Vote taken: Favourable opinion.

B.10 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Regulation (EU) 2023/915 as regards maximum levels of ergot sclerotia and ergot alkaloids in food

Following a detailed examination of the information provided by the stakeholders at the ergot alkaloid forum on 13 October 2023, it is concluded that the lower maximum levels foreseen to become applicable as from 1 July 2024 are not yet achievable for ergot sclerotia in unprocessed rye grains and for ergot alkaloids in milling products of wheat (*with an ash content lower than 900 mg/100 g dry matter)*, rye milling products and rye placed on the market for the final consumer because of an increase in the prevalence of ergot sclerotia and ergot alkaloids in cereals due to climatic conditions. It is therefore foreseen to defer the application of the lower maximum levels for ergot sclerotia in unprocessed rye grains for one year and for ergot alkaloids in milling products of wheat (*with an ash content lower than 900 mg/100 g dry matter*), rye milling products and rye placed on the market for the final consumer for four years. The following declaration was made by the delegation of Germany: *"Germany expresses strong concerns regarding the postponement of the entry into force of the lower maximum levels for ergot sclerotia. The former agreed lowered maximum levels are obviously needed with a view to consumer health protection and an appropriate transitional period was granted in Regulation (EU) 2021/1399. The timeline has been known to all parties involved for a long time. Therefore, it is hardly understandable that the postponement has been introduced at the last moment. Furthermore, technical possibilities to achieve the lowest possible levels have been available for some time, already".*

Vote taken: Favourable opinion.

B.11 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Regulation (EU) 2023/915 as regards maximum levels of nickel in certain foodstuffs

The Commission presented the draft, explained its contents and the changes that were made, following recent Member States' and stakeholders' comments. Following the increases of certain maximum levels (MLs) for cereals, in the ML category of 0.50 mg/kg only 2 cereals species remained (*rye and sorghum*). Therefore several Member States agreed to simplify the draft and to merge the ML categories of 0.50 and 0.80 mg/kg to one category with an ML of 0.80 mg/kg. Several Member States expressed their support for the draft and appreciate the recent changes that were made in order to address their comments. One Member State considered that, despite the changes that were made to alleviate its concerns, more time was needed to consult national stakeholders and it therefore voted against the draft. A Member State abstained because it needs more time for consulting its stakeholders and another one abstained because it considers the draft insufficiently proportionate.

Vote taken: Favourable opinion.

B.12 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 of sampling and analysis for the control of levels of nickel in foodstuffs and amending certain references

The Commission presented the draft and explained its contents, in relation with point B.12.

Vote taken: Favourable opinion.

B.13 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Implementing Regulation (EU) 2023/2782 laying down the methods of sampling and analysis for the control of the levels of mycotoxins in food as regards the method of sampling for dried herbs, herbal infusions (dried product), teas (dried product) and powdered spices

The results from recent research performed by a working group coordinated by the German Federal Institute for Risk Assessment (BfR) provide evidence that the sampling method for the control of plant toxins (*also applicable for the control of mycotoxins*) in dried herbs, herbal infusions (*dried product*), teas (*dried product*) and powdered spices as laid down in Implementing Regulation (EU) 2023/2782 does not guarantee the obtention of a sample that is representative for the sampled lot. It is therefore necessary to amend the sampling method by increasing the required weight of the incremental and aggregate samples to ensure that the obtained sample is representative for the sampled lot.

Vote taken: Favourable opinion.

B.14 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending and correcting Regulation (EU) 2023/915 on maximum levels for certain contaminants in food

The Commission presented the draft Commission Regulation amending and correcting Regulation (EU) 2023/915 on maximum levels for certain contaminants in food. During the first months of implementation of Commission Regulation (EU) 2023/915, it appeared that some entries and remarks needed to be further clarified, without changing their substance. This draft Regulation accommodates the various comments received from Member States thus avoiding confusion and enabling a proper enforcement of official controls on contaminants in food.

Vote taken: **Favourable opinion.**