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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*
12 June 2024

CIRCABC Link: *https://circabc.europa.eu/ui/group/55b2edd3-069e-40fd-ad4a-8b163f54ff1f/library/3de73da7-eac6-4836-bb15-1fb9162e44fb?p=1&n=10&sort=name_ASC*

SUMMARY REPORT

Section A Information and/or discussion

A.01 Feedback from the latest meeting of the Working Group of the PAFF on food contact materials:

The Commission services reported on the working group taking place on 6 and 7 May 2024. During the meeting the upcoming amendment to Regulation (EU) No 10/2011 was discussed in view of the feedback consultation which had been closed. Also an outlook was given for the authorisation of substances. The WG also discussed the revision process and in particular the project on sustainability, the draft text of the measure restricting the use ofBisphenol A (BPA) and the progress of the work on the implementation of Regulation (EU) 2022/1616. Handouts are available in the FCM document library.

A.02 Feedback and update on ongoing discussions related to contaminants in food:

A delegation raised questions as regards the scope of Commission Implementing Regulation (EU) 2020/1158 of 5 August 2020 on the conditions governing imports of food and feed originating in third countries following the accident at the Chernobyl nuclear power station. It was confirmed that currently products consigned from a country listed in Annex I to the Regulation in which the concerned ingredients (wild fruits of the genus *Vaccinium* or wild mushrooms) are not originating from a country listed in Annex I to the Regulation, fall in the scope of the Regulation. Furthermore, certain products listed in Annex II with a CN code and therefore falling within the scope of the Regulation contain much less than 20 % of wild mushrooms and/or wild fruits of the genus *Vaccinium*, while e.g. sugar confectionary, chocolate and bakery wares containing less than 20 % of wild mushrooms and/or wild fruits of the genus *Vaccinium* do not fall in the scope of the Regulation. It is appropriate to discuss these issues in more detail at the next meeting of the Working Group Industrial and Environmental contaminants in view of a possible amendment to Implementing Regulation (EU) 2020/1158.

Feedback was provided from the discussions at the meeting of the WG Industrial and Environmental contaminants on maximum levels of polycyclic aromatic hydrocarbons

(PAH), monitoring of furan-2(5H)-one and benzene-1,2 diol in conventionally smoked meat and meat products and smoked fish and fishery products and monitoring of bisphenol A and other bisphenols.

As regards the review of the maximum levels for PAH in smoked meat and meat products and smoked fish and fishery products it was clarified that the review does not concern the exemption/derogation provided for in Article 7 (3) in Regulation (EU) 2023/915 for traditionally smoked meat and smoked meat products and in Article 7 (4) for traditionally smoked fish and smoked fishery products. Based on recent available occurrence data it is appropriate to lower the maximum level for smoked fishery products, smoked sprats, canned smoked sprats, heat treated meat and heat traeated meat products placed on the market for the final consumer and smoked bivalve molluscs and to establish a maximum level for PAH in smoked cheese. It was clarified that the maximum level would not only apply to smoked food but also to foods with smoke taste (following the use of smoked ingredients, spices, …).

As regards the monitoring of furan-2(5H)-one and benzene-1,2-diol the Committee was informed that further work is needed on the method of analysis and to define appropriate analytical performance characteristic and on the formation of furan-2(5H)-one as processing contaminant in non-smoked foods. It was highlighted that the collection of occurrence data in smoked foods is necessary to enable the comparative risk assessment to be performed by EFSA between conventionally smoked food and food with smoked flavourings.

As regards the monitoring of Bisphenol A (BPA) (and other bisphenols) in food combined with follow-up investigations on the source of contamination, it was clarified that the aim of the monitoring recommendation is to gather information on the presence of bisphenol A (and other bisphenols in particular bisphenol S) and on the source of the presence (intentional use in food packaging, adventitious presence in food packaging, contamination at earlier stages in the production chain including from food contact articles, environmental contamination, any other possible source). In order to limit the burden, the investigations should only be performed from a certain indicative /trigger level of presence in food.

The Committee was informed that the discussions on these points will continue at the meeting of the WG Industrial and Environmental Contaminants in Food that takes place on 27 and 28 June 2024.

The delegation of Latvia made following statement:

"At the meeting of the Working Group on Industrial and Environmental contaminants on May 23rd 2024, Latvia expressed strong concern and considerations that the revision of the maximum levels for polycyclic aromatic hydrocarbons in conventionally smoked meat, fish and cheese products is not necessary at this stage and we would like to call on the Commission not to take immediate and rushed decisions without considering the current situation carefully as we believe that this is not linked to the need to protect the health of consumers during the transitional periods granted to smoke flavourings.

Latvia would like to point out that the smoke flavourings issue has already resulted in the endorsement not to renew the authorisations of all smoke flavourings. Only conventional smoking methods on wood can replace the use of smoke flavourings. Currently the industry must look for alternative solutions to replace smoke flavourings

in a tense period to provide the consumer with a smoked taste. This is currently a heavy burden on the industry.

Latvia is strongly concerned that initiation of a review of the maximum levels for polycyclic aromatic hydrocarbons in conventionally smoked meat, fish and cheese products without proper impact assessment while the transition period for smoking flavouring has not yet ended and the industry has not found solutions for new safe smoking flavourings would not be in line with the principle of proportionality and is not justified from the point of view of consumer health protection at the current stage.

To receive data on PAH levels in smoked cheese, we have started a study that will be completed at the end of this year. At the same time, we are planning a project on the current situation with PAH levels in food products next year. We do not yet have the data for further discussions on maximum levels.

At the same time, we would like to thank the Commission for pointing out that the review of maximum levels will not apply to derogations for traditionally smoked products and derogations will be maintained.

We will point out that the derogations provide an appropriate balance between the protection of consumer health and the possibility of providing consumers with traditional products with organoleptic characteristics of taste and smell that consumers demand and enjoy.

We would like to draw attention, that this is a very sensitive issue from a socio-economic point of view, as it provides work and development for a lot of food establishments, including small businesses in rural areas and coastal fishermen.

The meat processing industry will be particularly affected.

Latvia is concerned about the monitoring possibilities of furan-2(5H)-one and benzene-1,2-diol in smoked meat and meat products, cheese and fish at the moment, because no appropriate analytical methods have been developed."

Finally, the Committee was informed that a meeting of the Working Group Agricultural Contaminants will take place on 8 July 2024 and an overview of the topics that will be discussed was provided, in particular discussion on:

- the approach to be applied by the business operators as regards sampling and analysis when performing the obligatory autocontrols on the presence of mycotoxins and plant toxins;
- a maximum level for Δ-9 THC in hemp leaves for infusion;
- a draft Commission recommendation on quinolizidine alkaloids in food;
- the review of the maximum level for deoxynivalenol in wheat bran not placed on the market for the final consumer;
- the criteria/conditions for companies/processes to be listed as company able to reduce the presence of aflatoxins through sorting or other physical treatment – update of the guidance document.

Section B **Draft(s) presented for an opinion**

B.01 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 in collagen.

(PLAN/2024/1001)

A Commission representative presented the draft Commission Regulation amending Commission Regulation (EU) 2019/1871 as regards the application of reference points for action for nitrofurans and their metabolites in collagen. The presence of the nitrofuran metabolite semicarbazide (SEM) in certain processed products may arise during processing from naturally occurring compounds and is not related to an illegal treatment by nitrofurans. These foods are therefore exempted from the application of reference points for action for SEM to findings where only SEM is present in these processed products. Evidence has been provided that SEM is also formed during the production of collagen and therefore collagen should be added to the exempted processed products.

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) 2021/808 as regards its scope and certain performance criteria of analytical methods for residues of pharmacologically active substances used in food-producing animals.

(PLAN/2024/135)

A Commission representative presented the draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) 2021/808 as regards its scope and certain performance criteria of analytical methods for residues of pharmacologically active substances used in food-producing animals. Implementing Regulation (EU) 2021/808 lays down rules concerning the sampling and methods of analysis for residues of pharmacologically active substances in samples taken in the frame of control plans on residues in animals and food of animal origin. When the source of non-compliance is investigated, also fluids, excrements, feed or water can be analysed. Implementing Regulation (EU) 2021/808 is thus not primarily intended for the official control of feed where the criteria for validation (trueness, precision) as laid down in Regulation (EU) 2021/808 are not achievable, given the complexity of the feed matrix. Therefore, this amendment limits the scope of Commission Implementing Regulation (EU) 2021/808 to samples taken in the frame of national plans as defined in Article 3 of Commission Implementing Regulation (EU) 2022/1646. In addition, based on the Member States' experience in the implementation of the Regulation, certain performance criteria (precision, relative matrix effects) are amended to become achievable.

Vote taken: Favourable opinion.

B.03 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 sorbic acid (E 200) and potassium sorbate (E 202) and the Annex to Commission Regulation (EU) No 231/2012 as regards the specifications for sorbic acid (E 200), potassium sorbate (E 202) and propyl gallate (E 310)

(PLAN/2024/1027)

A Commission representative presented the draft Commission Regulation authorising an extension of use of sorbic acid (E 200) and potassium sorbate (E 202) in fruit-flavoured water-based gelatine desserts and amending the specifications for sorbic acid (E 200), potassium sorbate (E 202) and propyl gallate (E 310) as a follow-up of their re-evaluations by EFSA. The extended use of sorbic acid (E 200) and potassium sorbate (E 202) in fruit-flavoured water-based gelatine desserts is not liable to have an effect on human health and consequently it is not necessary to seek the opinion of the Authority. Hence it is appropriate to authorise the extension of use of sorbic acid (E 200) and potassium sorbate (E 202). EFSA concluded that the current specifications of sorbic acid (E 200), potassium sorbate (E 202) and propyl gallate (E 310) were to be adapted. In particular, the following modifications of the EU specifications are appropriate: (1) to lower the maximum limits of toxic elements, (2) to include maximum limits for metals used as catalyst (for E 200 and E 202 only), (3) to include a definition of the food additive (for E 310 only). Furthermore, it is appropriate to amend the description of potassium sorbate (E 202) to refer not only to its powder form but also to its granular form, since the former form is produced from the latter by milling and both physical forms, powder and granular, have the same purity. A transitional period will be granted to allow food business operators to adapt to the new specifications.

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 specific labelling requirements of the novel food partially hydrolysed protein from spent barley (*Hordeum vulgare*) and rice (*Oryza sativa*)

(PLAN/2024/797)

A Commission representative presented the draft Commission Implementing Regulation authorising a change of the specific labelling requirements of the novel food 'partially hydrolysed protein from spent barley (*Hordeum vulgare*) and rice (*Oryza sativa*)'. In particular, the designation of the novel food is to be changed to 'partially hydrolysed protein from barley and rice'. As the change of the specific labelling requirements, in particular the designation of the novel food, is not liable to have an effect on human health a safety evaluation by EFSA was not necessary.

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 specifications of the novel food *Schizochytrium* sp. oil rich in DHA and EPA

(PLAN/2024/796)

The Commission representative presented the draft Commission Implementing Regulation authorising a change of the specifications of the novel food *Schizochytrium* sp. oil rich in DHA and EPA. This change concerns levels of DHA which are to be decreased from the current authorised level of equal or greater than 22,5% to equal or greater than 15,0%. As the change of the specifications of the novel food is not liable to have an effect on human health, due to lower levels of DHA than previously assessed by EFSA as safe, a safety evaluation by EFSA was not necessary.

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 juice of the stems of the *Angelica keiskei* plant (Ashitaba stem juice) as a novel food and amending Implementing Regulation (EU) 2017/2470

(PLAN/2024/672)

A Commission representative presented the draft Commission Implementing Regulation authorising the placing on the market of the juice of the stems of the *Angelica keiskei* plant (Ashitaba stem juice) as a novel food to be used in food supplements intended for the adult population excluding pregnant and lactating women. This authorisation is supported by a positive EFSA opinion.

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 and the conditions of use of the novel food protein extract from pig kidneys

(PLAN/2023/1921)

A Commission representative presented the draft Commission Implementing Regulation authorising the change in the conditions of use and of the specifications of the novel food protein extract from pig kidneys to replace the mention of specific forms that this novel food can be made available to the consumer by no mention of any specific forms so that any form can be used provided the maximum authorised use levels are respected. An EFSA opinion underpinning this proposal was not deemed necessary as data provided by the applicant and data available from previous applications clearly demonstrated that the form this novel food is presented to the consumer plays no role in its bioavailability and safety.

Vote taken: Favourable opinion.

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) on the use of bisphenol A (BPA) and other bisphenols and their derivatives with harmonised classification for specific hazardous properties in certain materials and articles intended to come into contact with food, amending Regulation (EU) No 10/2011 and repealing Regulation (EU) 2018/213

(PLAN/2023/1013)

A Commission representative presented the draft Regulation, elaborating on the development of the text, including discussions held during meetings of the Food Contact Material (FCM) Working Group of the Standing Committee and contributions

from Member States as well as the feedback period held February – March 2024. The feedback period had generated over 200 comments from all stakeholders, which had been taken into consideration.

Some Member States stated that they consider the transitional periods too long; the Commission representative acknowledged that whilst opinions differed on the length of the transitional periods, an appropriate balance had been achieved, taking into account the need to ensure supply chain continuity across the whole of the Union market. On the other hand, some Member States indicated that they consider the transitional periods still challenging and welcomed the wording in Article 12(3) that allows repeat-use food contact articles to remain in use by professional food business operators until the end of the article's service life. Nonetheless, the Commission acknowledged that should significant supply issues occur in the future, concerning replacement of such articles, it would be open to discussing the issues and examining any supporting data. By the same token, the Commission representative stated that it is committed to reassessing the need to maintain the derogations provided for in Annex II.

Finally, the Committee agreed that development of work on analytical methodology was important to support implementation of the Regulation.

One Member State indicated not to support the draft Commission Regulation considering the transitional periods too long.

France made the following statement:

"Considérant l'importance de ce nouveau règlement pour la protection des consommateurs européens les autorités françaises soutiennent ce texte mais demandent l'inscription au procès-verbal des deux points de divergence sur les dérogations et périodes de transition.

Dérogation permanentes

Les autorités françaises soulignent que des dérogations permanentes à l'interdiction de l'usage du BPA dans les cuves de plus de 1000L et dans les membranes de filtration en polysulfone sont inscrites dans ce règlement. Ces dérogations sont peu étayées scientifiquement et questionnent sur la nécessité de maintenir ces exemptions.

Les autorités françaises auraient préféré des périodes de transition adaptées à ces cas particuliers pour des considérations techniques afin de permettre le développement d'alternatives.

Durée des périodes de transition

Les autorités françaises considèrent que les périodes de transition prévues pour certains produits, tels que les fruits, légumes et produits de la pêche conditionnés dans des emballages revêtus, sont trop longues (36 mois + 12 mois d'écoulement des stocks) sachant que de nombreuses alternatives sont déjà présentes et disponibles sur le marché européen proposées par de nombreux opérateurs.

Les autorités françaises souhaiteront également inscrire en point d'attention le fait qu'une méthode de vérification de l'absence de BPA a été développée par son laboratoire national de référence pour la mise en œuvre de la loi française d'interdiction de cette substance en 2012. Cette méthode d'extraction est largement utilisée par les industries françaises et pourra servir de support pour l'élaboration de la méthode d'analyses par extraction par l'EURL. Ceci permettra de vérifier

l'interdiction des matériaux et objets à base de BPA ou de ceux fabriqués avec des dérivés de BPA qui contiennent cette substance.

Traduction de courtoisie:

French authorities request that the following points be included in the minutes of the SCOPAFF meeting of 12th June 2024.

Points of divergence

1) Permanent derogations

French authorities regret that permanent derogations from the ban on the use of BPA in tanks of more than 1000L and in polysulphone filtration membranes are included in this regulation. There is little scientific support for these derogations, which raises questions about the need to maintain them.

French authorities would have preferred transition periods adapted to these specific cases for technical reasons, to allow the development of alternatives.

2) Length of transition periods

French authorities consider that the transition periods provided for certain products, such as fruit, vegetables and fishery products packaged in coated packaging, are too long (36 months + 12 months for stocks to run out) given that many alternatives are already present and available on the European market, proposed by numerous operators.

Point of attention:

French authorities would also like to highlight the fact that a method for verifying the absence of BPA has been developed by its national reference laboratory for the implementation of the French law banning this substance since 2012. This extraction method is widely used by French industries and could serve as a basis for the development of the extraction analysis method by EURL. This will make it possible to verify the ban on BPA-based Food contact materials or those manufactured with BPA derivatives that contain this substance."

Sweden made the following statement:

"According to the Chemicals Strategy for Sustainability of October 2020, the European Commission will extend the generic approach to risk management to ensure that consumer products – including, among other things, Food Contact Materials - do not contain chemicals that, inter alia, affect the reproductive or the endocrine system. The Food Contact Materials Regulation is among the relevant legal acts listed in the annex to the strategy.

Moreover, according to the strategy, the European Commission will define criteria for essential uses to ensure that the most harmful chemicals are only allowed if their use is necessary for health, safety or is critical for the functioning of society and if there are no alternatives that are acceptable from the standpoint of environment and health. Guiding criteria and principles for the essential use concept in EU-legislation dealing with chemicals were published in April 2024.

In its assessment of Regulatory needs for bisphenols, dated 16 December 2021, ECHA concluded that there are several bisphenols with known or potential hazard for reproductive toxicity and/or endocrine disrupting properties. Consequently, there is an

urgent need to prohibit the use of other bisphenols than bisphenol A and bisphenol S. The regulation should therefore be reviewed in a near future."

Vote taken: Favourable opinion.