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*
24 April 2024

CIRCABC Link: *https://circabc.europa.eu/ui/group/55b2edd3-069e-40fd-ad4a-8b163f54ff1f/library/e3b22d12-6305-457e-a0af-1743ff65f565?p=1&n=10&sort=name_ASC*

SUMMARY REPORT

A.01 EFSA 2022 Report on the results from the monitoring of veterinary medicinal product residues and other substances in live animals and animal products

EFSA presented the report to the Committee. A total of 600,320 samples were reported with only 0.18% of non-compliant samples; this percentage is comparable to the results of previous years.

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

The Commission provided feedback on the meeting of the FCM Experts Working Group of the SC-PAFF that took place on 22 March 2024. At that meeting, the Commission provided an overview of the feedback received from stakeholders on the draft Regulation concerning rules on the use of bisphenol A (BPA) and other bisphenols, and discussed the main points received. The meeting was informed that a final discussion would take place at the Expert Working Group meeting planned for 6 – 7 May with a vote at the PAFF meeting scheduled on 12 June. The draft amendment to Commission Regulation (EU) No 10/2011 concerning plastic FCMs was also discussed, which concerns content [quality] of the legal text and the provisions therein (the 'quality amendment'). At the time of the Working Group meeting, the document had been launched for public feedback. The Commission presented the elements of the amendment and had an exchange with Member States on the main aspects, including on purity criteria, labelling and biocides. The timeline for vote was also stated as being the 12 June PAFF meeting but there was also recognition of the technical and challenging topics being addressed that could slow down the process. The amendment is also aimed at ensuring coherence with the Regulation on recycling processes for plastic FCM (Commission Regulation (EU) 2022/1616). An update on the additional planned amending text for this Regulation, as well as the format of the planned authorisation Decisions and the Register was given by the Commission. Finally, the Commission gave some short feedback on the Workshop held by a contractor on the study being undertaken concerning information exchange, compliance and enforcement in the FCM supply chain.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) …/… amending Implementing Regulation (EU) 2022/1646 as regards additional content of the national risk-based control plans and the national randomised surveillance plan, the submission of those plans and data by Member States and minimum sampling frequencies

This amendment to the regulation clarifies the provisions related to the content and submission of the control plans and data of the control plans on residues of veterinary medicinal products. A change in the mandatory sampling frequency for controls of the presence of substance group A3b (plant protection products and biocides) in all commodity groups was made because these controls can be performed also under the framework for control plans on pesticide residues. Member States can choose under which framework (pesticide residues or residues of veterinary medicinal products) they take samples and therefore a mandatory sampling without fixed percentage was introduced.

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 as regards the use of powdered cellulose (E 460(ii)) and glucono-delta-lactone (E 575) in unripened soft spreadable cheese products

The Commission presented the draft Commission Regulation authorising an extension of use of powdered cellulose (E 460(ii)) and glucono-delta-lactone (E 575) in unripened soft spreadable cheese products under food category 01.7.6 ‘Cheese products (excluding products falling in category 16)’. The use of powdered cellulose (E 460(ii)) as a stabiliser and of glucono-delta-lactone (E 575) as an acidity regulator in unripened soft spreadable cheese products is not liable to have an effect on human health and therefore it is not necessary to seek the opinion of the Authority. Hence it is appropriate to authorise the extension of use of powdered cellulose (E 460(ii)) and glucono-delta-lactone (E 575).

Vote taken: Favourable opinion.

B.03-B.11 Smoke flavouring primary products - General discussion:

On 16 November 2023, the European Food Safety Authority published several opinions which stated that, based on the available scientific evidence, it could not rule out concerns regarding genotoxicity for any of the 8 smoke flavourings primary products currently on the market. As a consequence, the Commission proposed decisions to refuse the renewals of the authorisation of SF-001, SF-002, sf-003, SF-004, SF-005, SF-006, SF-08 and SF-009 and the related Implementing Regulation describing the phase-out periods. These phase-out periods, for the addition in foods of the above smoke flavourings will be 5 years (until 1st July 2029) for food categories 1.7 (cheese and cheese products), 8 (Meat), 9.2 (Processed fish and fishery products including crustaceans and molluscs), 9.3 (Fish roe) and their corresponding sub-categories and 2 years (until 1st July 2026) for all other food categories.

During the discussion, many Member States welcomed the proposals as the best-balanced option based on the EFSA opinions but taking also under consideration the challenges for the producers and users of smoke flavourings. Most Member States

indicated that a comparative risk assessment with conventional smoking processes should be performed as a follow-up to these opinions by EFSA. Some Member States stated that the measures will force the food industry to come back to conventional smoking processes that may potentially entail more risks for health. They suggested that more information and discussions would be needed for developing well-founded risk management decisions. A Member State noted that it could support the suggested measures only if, in the extended phase-out period of 5 years, also food products marketed as vegan alternatives to products of animal origin would be included (for example vegan "sausages"). Another Member State considered the phase out periods to be too extensive and proposed a period of 18 months for the production and use of smoke flavourings and a transition period of 9 months for the end of sale of food already produced with these flavourings.

The Commission thanked all Member States for their contribution and comments and informed the Committee that a dedicated meeting of the Working Group on Industrial and Environmental Contaminants would be held in the second half of May to discuss the review of the current maximum levels for polycyclic aromatic hydrocarbons in smoked meat and fish and to establish maximum levels for PAH in smoked cheese taking into account the most recent occurrence data. Furthermore, a monitoring recommendation for the presence of furan-2(5H)-one and benzene-1,2-diol in smoked meat, cheese and fish products will be discussed which would aim at gathering occurrence data in view of possible regulatory measures as regards the presence of furan-2(5H)-one and benzene-1,2-diol in these products. Furthermore, it was confirmed that the Commission is finalising a mandate for EFSA to perform a comparative risk assessment on the different processes giving a smoke flavour to food. Once finalised the Commission shall share the mandate with the Member States.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision refusing the renewal of the authorisation of Scansmoke PB 1110 (SF-001) as a smoke flavouring primary product

The Commission presented to the Committee the draft act refusing the renewal of the authorisation of Scansmoke PB 1110 (SF-001) as a smoke flavouring primary product. This product may continue to be placed on the market until 1 July 2029.

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision refusing the renewal of the authorisation of Zesti Smoke Code 10 (SF-002) as a smoke flavouring primary product

The Commission presented to the Committee the draft act refusing the renewal of the authorisation of Zesti Smoke Code 10 (SF-002) as a smoke flavouring primary product. This product may continue to be placed on the market until 1 July 2029.

Vote taken: Favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision refusing the renewal of the authorisation of Smoke Concentrate 809045 (SF-003) as a smoke flavouring primary product

The Commission presented to the Committee the draft act refusing the renewal of the authorisation of Smoke Concentrate 809045 (SF-003) as a smoke flavouring primary product. This product may continue to be placed on the market until 1 July 2029.

Vote taken: Favourable opinion.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision refusing the renewal of the authorisation of Scansmoke SEF 7525 (SF-004) as a smoke flavouring primary product

The Commission presented to the Committee the draft act refusing the renewal of the authorisation of Scansmoke SEF 7525 (SF-004) as a smoke flavouring primary product. This product may continue to be placed on the market until 1 July 2029.

Vote taken: Favourable opinion.

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision refusing the renewal of the authorisation of SmokEz C-10 (SF-005) as a smoke flavouring primary product

The Commission presented to the Committee the draft act refusing the renewal of the authorisation of SmokEz C-10 (SF005) as a smoke flavouring primary product. This product may continue to be placed on the market until 1 July 2029.

Vote taken: Favourable opinion.

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision refusing the renewal of the authorisation of SmokEz Enviro-23 (SF-006) as a smoke flavouring primary product

The Commission presented to the Committee the draft act refusing the renewal of the authorisation of SmokEz Enviro-23 (SF-006) as a smoke flavouring primary product. This product may continue to be placed on the market until 1 July 2029.

Vote taken: Favourable opinion.

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision refusing the renewal of the authorisation of proFagus-Smoke R709 (SF-008) as a smoke flavouring primary product

The Commission presented to the Committee the draft act refusing the renewal of the authorisation of proFagus-Smoke R709 (SF-008) as a smoke flavouring primary product. This product may continue to be placed on the market until 1 July 2029.

Vote taken: Favourable opinion.

B.10 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision refusing the renewal of the authorisation of Fumokomp (SF-009) as a smoke flavouring primary product

The Commission presented to the Committee the draft act refusing the renewal of the authorisation of Fumokomp (SF009) as a smoke flavouring primary product. This product may continue to be placed on the market until 1 July 2029.

Vote taken: Favourable opinion.

B.11 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Implementing Regulation (EU) No 1321/2013 as regards the deletion of entries SF-001 to SF-010 from the Union list of authorised smoke flavouring primary products

The Commission presented to the Committee the draft act amending Implementing Regulation (EU) No 1321/2013 as regards the deletion of entries SF-001 to SF-010 from the Union list of authorised smoke flavouring primary products. Foods of categories 1.7 (cheese and cheese products), 8 (Meat), 9.2 (Processed fish and fishery products including crustaceans and molluscs), 9.3 (Fish roe) and their corresponding sub-categories, to which those smoke flavouring primary products are added should be allowed to be placed on the market until 1 July 2029 and to remain on the market until their date of minimum durability or use-by date. Foods of all other categories to which those smoke flavouring primary products are added should be allowed to be placed on the market until 1 July 2026 and to remain on the market until their date of minimum durability or use-by date.

Vote taken: Favourable opinion.

B.12 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards the removal of the flavouring substance Benzene-1,2-diol (FL No. 04.029) from the Union list

The Commission presented to the Committee the draft act amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards the removal of the flavouring substance Benzene-1,2-diol (FL No. 04.029) from the Union list. Foods to which Benzene-1,2-diol (FL No. 04.029) has been added and which have been placed on the market in the Union or which are in transit from third countries to the Union before the entry into force of this Regulation should be allowed to be marketed in the Union until their date of minimum durability or use-by date.

Vote taken: Favourable opinion.

B.13 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU)…. amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use of the novel food 2´-Fucosyllactose, and as regards the specifications of the novel food 2´-Fucosyllactose produced with a derivative strain of *Escherichia coli* BL21

The Commission presented to the Committee the draft act authorising the change in the conditions of use of then novel food 2´-Fucosyllactose (2'-FL) to increase the use levels in infant formulae and follow-on formulae and changes in the specifications of 2'-FL produced with a derivative strain of *E. coli* BL21 to authorise increased levels in residual endotoxins. The proposed amendments are supported by positive EFSA opinions.

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 2´-Fucosyllactose 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 2´-Fucosyllactose (2'-FL) produced by derivative strains of *Escherichia coli* W (ATCC 9637) as a novel food to be used in the same food applications as the currently authorised 2´-Fucosyllactose produced by other companies. This authorisation is supported by a positive EFSA opinion.

Vote taken: Favourable opinion.

B.15 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU)…. draft Commission Implementing Regulation (EU) authorising the placing on the market of Lacto-N-fucopentaose I/2'-Fucosyllactose ('LNFP-I/2'-FL') mixture produced using a derivative strain of *Escherichia coli* K-12 DH1 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 a mixture of Lacto-N-fucopentaose I/2'-Fucosyllactose ('LNFP-I and 2'-FL') mixture produced using a derivative strain of *Escherichia coli* K-12 DH1 as a novel food to be used in a number of food applications identical to the uses of other Human identical Milk Oligosaccharides (HiMOs). This authorisation is supported by a positive EFSA opinion.

Vote taken: Favourable opinion.

B.16 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) authorising the placing on the market of Schizochytrium sp. (CABIO-A-2) oil 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 Schizochytrium sp. (CABIO-A-2) oil as a novel food on the basis of a positive EFSA opinion. Schizochytrium sp. (CABIO-A-2) oil is to be used in infant formula and follow-on formula as defined in Regulation (EU) No 609/2013.

Vote taken: Favourable opinion.

B.17 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) authorising the placing on the market of Schizochytrium limacinum (TKD-1) oil 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 Schizochytrium limacinum (TKD-1) oil as a novel food on the basis of a positive EFSA opinion. Schizochytrium limacinum (TKD-1) oil is to be used in infant formula and follow-on formula as defined in Regulation (EU) No 609/2013.

Vote taken: Favourable opinion.

B.18 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) authorising the placing on the market of isomaltulose powder 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 isomaltulose powder as a novel food on the basis of a positive EFSA opinion. Isomaltulose powder as a replacement for sucrose is to be used in all foods, excluding foods and drinks intended specifically for infants and young children.

Vote taken: Favourable opinion.

B.19 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 Yarrowia lipolytica yeast biomass

The Commission presented to the Committee the draft act amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use and the specifications of the novel food Yarrowia lipolytica yeast biomass on the basis of a positive EFSA opinion. The draft act concerns the authorisation of a change in the conditions of use of the novel food, in particular the extension of its use to a number of foods, and a change of the specifications of the novel food concerning the addition of limits for certain heavy metals.

Vote taken: Favourable opinion.