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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*
21 June 2021

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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 (COM) gave feedback from the Working Group (WG) on Food Contact Materials (FCM) of the SC-PAFF, held 26th – 27th April 2021. It explained that it (SANTE G4) had given a presentation concerning EU action on melamine-bamboo FCM under the Food Fraud Network (FFN), including information collected so far, and highlighted issues that relate to import duties. Hungary also gave a presentation of its findings. The COM presentation included a schematic on who is expected to do what. The discussion preceded the dedicated enforcement meeting with Member States on 6th May. Since then, a letter has been sent to industry stakeholders and information distributed via various channels including the FFN through the iRasff system, the Customs information system and to Border Control Posts (BCPs).

The COM gave an update in the WG meeting on plastic FCM. It explained that nearly stable text for the 16th amendment and the update to the Recycling regulation were expected to have been available at around the time of the WG. However, in both cases, analysis showed that further work was required (*which COM noted is still on-going*). A short discussion took place on the main issues to be covered in the 16th amendment to Regulation (EU) No 10/2011, including in particular new migration limits for phthalates, as well as various other matters such as the transition period, with a view to improve wording concerning 'first placed on the market'.

The COM explained that a recast or replacement of the present Regulation (EC) No 282/2008 on the recycling of plastics is expected; at the time of the WG meeting, a text had been expected by the end of May. However, the COM informed the SC-PAFF that this date could not be met, as extensive redrafting is still on-going. In part to resolve some of the complications in transition, the Commission will now put forward a text that will address all forms of plastic recycling in its scope. This will be discussed in detail in the next WG and a text will follow thereafter.

During the WG, the COM had also given an update on the initiative on ceramic and vitreous FCM, including an invitation to Member States for a focus group in the context of the study supporting the impact assessment. It explained that this focus group is aimed at gathering their views regarding the possible impacts of significantly lowering limits for lead and cadmium, and introducing another six limits for other metals, as well as considering what impact mitigating provisions would have on MS Competent Authorities (*controls, National Reference Laboratories, managing derogations for traditional producers, transition schemes*). The timeline for this initiative still needs to be confirmed.

Concerning the evaluation of the FCM legislation, the COM plans to adopt a Staff Working Document this year. Further activity on the revision of the legislation will be communicated – likely timeframe is completion in the first half of 2023.

Belgium had given a presentation on cyclo-di-BADGE from coated metal cans. Although no serious risk has been identified, uncertainties remain and the COM had been asked whether EFSA could be asked to undertake a risk assessment and whether a measure for cyclo-di-BADGE could be introduced at EU level. The Commission services had explained that the results of work being undertaken by industry should first be assessed; for non-intentionally added substances (NIAS), this will be addressed under the overall FCM revision.

Various other topics were discussed or presented in the WG including on the new e-submission system, on testing guidelines (EU-RL), on a virtual workshop on the enforcement of the Good Manufacturing Practices (GMP) and other issues concerning beeswax wrapping, lignocellulose and active coffee filters. Documents from the meeting are available on the Commission's FCM document library page.

A.02 Brexit - implementation of the withdrawal agreement – Q&A session.

No questions were raised by the Committee, which was informed that the point would no longer systematically be on the agenda, but that questions or requests for clarification as regards Brexit and the implementation of the withdrawal agreement for topics falling within the remit of this section of the Committee can always be raised under any other business at future meetings.

A.03 Feedback on discussions in recent meetings of the Working Groups on diverse contaminants:

- endorsement of the changes as regards the Maximum Levels (MLs) for dioxins and PCBs in food in view of a targeted stakeholder consultation:

A comprehensive review of the EU legislation on dioxins and dioxin-like PCBs in food is foreseen, as follow-up the EFSA risk assessment on dioxins and dioxin-like PCBs from November 2018, which recommended that the review is done once the Toxic Equivalent Factors (TEFs) for dioxins and dioxin-like PCBs have been reviewed by the World Health Organisation (WHO). WHO confirmed it would be able to finalise this review by the end of 2022. In the meantime, it is appropriate to update the legislation mainly to include maximum levels for foods not yet covered by the EU legislation (such as goat meat, duck eggs, …) and to lower the maximum level for milk and dairy products. The Committee agreed to submit the foreseen amendments for a targeted stakeholder consultation.

- endorsement of the changes as regards MLs for ochratoxin A:

EFSA published in May 2020 its updated risk assessment on ochratoxin A in food. It was concluded that the calculated Margin of Exposure (MOE) for carcinogenic effects indicate a possible health concern for some consumer groups. Taking into account the outcome of this EFSA opinion, the setting of maximum levels for ochratoxin A in foods not yet covered by legislation and the lowering of existing maximum levels have been discussed, so as to ensure a high level of human health protection. It was noted that a possible specific maximum level for ochratoxin A in date juice still needs to be discussed once the requested additional information, committed to be available by the end of August 2021, is provided by the affected stakeholder organisation. No further comments were made and the Committee was informed that the foreseen changes to the maximum levels of ochratoxin A will be submitted for opinion at a next meeting of the Committee.

- endorsement of the changes as regards MLs for hydrocyanic acid:

EFSA published in April 2019 on opinion on the health risks related to the presence of cyanogenic glycosides in foods other than raw apricot kernels. In order to ensure a high level of public health protection, maximum levels for linseed and derived products, almonds, cassava and cassava products have been discussed. A reaction was received from a stakeholder organisation as regards the foreseen maximum level for ground, milled, cracked and chopped linseed which requires further clarification before the comment can eventually be taken into account. On the other proposed maximum levels no further comments were noted.

- update on the discussions regarding the review and new regulatory provisions on acrylamide in food and endorsement of the approach, in view of a targeted stakeholder consultation:

The Committee was informed of the ongoing discussions on acrylamide in food:

1) review of the existing benchmark levels,

2) establishment of benchmark levels for foods not yet covered and

3) establishment of maximum levels for certain foods.

Further technical discussions were foreseen during the working group meeting the day after the Committee meeting. No further comments were made in view of a targeted stakeholder consultation on the benchmark and maximum levels.

- discussion and agreement on the regulatory approach for glycidyl esters and 3-MCPD esters in food other than foods currently regulated under Regulation (EC) No 1881/2006:

Maximum levels for 3-MCPD esters and glycidyl esters have been established for vegetable oils, fish oils and oils derived from other marine organisms, infant formula, follow-on formula and young child formula. In the RASFF, it is noted that high levels of glycidyl esters and 3-MCPD esters occur in e.g. biscuits. In order to ensure a high level of human health protection and a uniform approach on enforcement across the EU, it is necessary to provide for additional provisions that regulate the presence of glycidyl esters and 3-MCPD esters in foods.

- update on perfluoroalkylated substances in food:

The Commission informed on the outcome of the 2020 EFSA opinion on perfluoroalkylated substances in food, in which it is concluded that parts of the European population exceed the tolerable weekly intake, which is of concern. For some commodity groups sufficient data are available to allow the establishment of maximum levels and also sufficient analytical capability is available among the laboratories. This is the case for commodities of animal origin. For other commodities, which are relevant contributors to the exposure, currently no maximum levels can be considered due to lacking occurrence data or due to the need to improve the sensitivity of the analytical methods. This is the case for fruits, vegetables and food for infants and young children. For those commodities further work is proposed under a monitoring Recommendation. Member States have been invited to comment on the draft Regulation on Maximum Levels and on the draft monitoring Recommendation. Both proposals will be further discussed in the Working Group on Industrial and Environmental contaminants in food.

- update and exchange of views on other topics discussed:

The Committee was also informed that a targeted stakeholder consultation is foreseen:

1) on a draft Commission Recommendation on the monitoring of the presence of glycoalkaloids in potatoes and potato products;
2) on a draft Commission Implementing Regulation 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 and
3) on a draft Commission Implementing Regulation laying down the methods of sampling and analysis for the control of the levels of plant toxins in foodstuffs and repealing Regulation (EU) 2015/705.

The sampling procedure for the control of plant toxins is foreseen to be the same as the sampling provisions for the control of mycotoxins.

Furthermore, the attention was drawn to the frequent findings of high levels of pyrrolizidine alkaloids in oregano and cumin seeds as notified in the Rapid Alert System for Food and Feed. It is of major importance that the food business operators take without delay the necessary actions to prevent the presence of pyrrolizidine alkaloids in oregano and cumin seeds to ensure a high level of human health protection and to ensure compliance with the maximum levels entering into application on 1 July 2022.

B.01 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 and Implementing Regulation (EU) 2020/484 authorising the placing on the market of lacto-N-tetraose as a novel food under Regulation (EU) 2015/2283.

The Commission presented to the Committee the draft Commission Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods, Commission Decision 2008/968/EC authorising the placing on the market of arachidonic acid-rich oil from *Mortierella alpina* as a novel food ingredient and Implementing Regulation (EU) 2020/484 authorising the placing on the market of lacto-N-tetraose as a novel food. The measure is intended to correct 3 errors in the Union list of novel foods. The first error is in the entry of the authorised novel food 'Arachidonic acid-rich oil from the fungus *Mortierella alpine'* where the specified food category 'Foods for special medical purposes for premature infants as defined in Regulation (EU) No 609/2013' for this novel food is not fully correct as it can be interpreted that the novel food can only be used for that category in premature infants. The second error corresponds to the novel food 'Calcium L-Methylfolate' as this novel food, which was authorised under certain conditions of use by the Irish competent authority in January 2008 under the provisions of the former novel food regulation (EC) No 258/97, was erroneously not included in the initial Union list. The third error is related to the authorised novel food 'Lacto-N-tetraose (microbial source)' in particular on its chemical formula and the minor ingredient 'lacto-N-triose II'.

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 change of the conditions of use of the novel food astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470.

The Commission presented to the Committee the draft Commission Implementing Regulation (EU) authorising a change in the conditions of use of the novel food astaxanthin-rich oleoresin from *Haematococcus pluvialis* currently authorised for use in food supplements for the general population at levels of 8 mg/day. The proposed measure, which is underpinned by an EFSA opinion, authorises the change in the conditions of use of food supplements containing astaxanthin-rich oleoresin from *Haematococcus pluvialis* to restrict their use only for persons above 14 years of age.

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) authorising the placing on the market of *Schizochytrium* sp. (FCC-3204) oil as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) 2017/2470.

The Commission presented to the Committee the draft Commission Implementing Regulation (EU) authorising the placing on the market of Schizochytrium sp. (FCC-3204) oil as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) 2017/2470. The measure authorises the placing on the market of Schizochytrium sp. (FCC-3204) oil as a novel food for use in infant formula and follow-on formula as defined in Regulation (EU) No 609/2013 and in food supplements as defined in Directive 2002/46/EC for the general population above 3 years of age.

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) authorising a change in the specifications of the novel food coriander seed oil *from Coriandrum Sativum* and amending Implementing Regulation (EU) 2017/2470.

The Commission presented to the Committee the draft proposal Commission Implementing Regulation (EU) authorising a change in the specifications the novel food coriander seed oil from *Coriandrum Sativum* and amending Implementing Regulation (EU) 2017/2470. The measure authorises a change in the specifications of the novel food coriander seed oil from *Coriandrum sativum*. In particular, this change concerns an increase of the maximum level of acid value in the Coriander seed oil, from 2,5 mg KOH/g of food as indicated in the Union list of novel foods, to ≤ 3,5 mg KOH/g of food and the modification of the colour description, from slight yellow colour to yellowish to brown colour.

Vote taken by written procedure: Favourable opinion.

B.05 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 inclusion of 4-amino-5-(3-(isopropylamino)-2,2-dimethyl-3oxopropoxy)-2-methylquinoline-3-carboxylic acid in the Union list of flavouring substances.

The Commission presented the draft Commission Regulation (EU) authorising the above-mentioned substance to be included in the Union list of flavourings with the reference FL no. 16.130, and the specifications and conditions of use as proposed, on the basis of the EFSA opinion.

Vote taken by written procedure: Favourable opinion.

B.06 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 inclusion of 2-(4-Methylphenoxy)-W-1H-pyrazol-3-yl-W-(thiophen-2-ylmethyl) acetamide in the Union list of flavouring substances.

The Commission presented the draft Commission Regulation (EU) authorising the above-mentioned substance to be included in the Union list of flavourings with the reference FL no. 16.133, and the specifications and conditions of use as proposed, on the basis of the EFSA opinion.

Vote taken by written procedure: Favourable opinion.

B.07 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 opium alkaloids in certain foodstuffs.

The draft Commission Regulation establishes maximum levels for morphine equivalents (*sum of morphine and codeine, whereby to codeine a factor of 0.2 is applied*) in poppy seeds and bakery products containing poppy seeds. It is also provided that the food business operator supplying the poppy seeds to the food business operator manufacturing the bakery products shall provide all the necessary information, including analytical data, where appropriate, to enable the manufacturer of the bakery products to place products on market compliant with the maximum level.

Vote taken by written procedure: Favourable opinion.

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation imposing special conditions governing the import of feed and food originating in or dispatched from Japan following the accident at the Fukushima nuclear power station and repealing Implementing Regulation (EU) No 2016/6.

In 2011, following the Fukushima Daiichi nuclear power plant accident, the EU reinforced its controls on imports of feed and food from certain regions of Japan. Since then, the Commission has regularly reviewed these measures applying defined criteria for listing/delisting prefecture/food combinations for which pre-export testing is required. This has resulted in a progressive alleviation of the measures. For this review, the same criteria for listing and delisting prefecture/food combinations have been applied based on the 2019 and 2020 monitoring data. Taking into account comments received from the Japanese authorities shortly before the meeting, further adjustments within the defined criteria (*wild mushrooms instead of mushrooms, wild bracken instead of bracken and dried persimmon instead all persimmon*) were proposed and accepted by the Committee. Several Member States, while supporting the proposed measure, highlighted the appropriateness of a further alleviation and a review of the criteria for the next review. One delegation could not support the draft measure as it was of the opinion that, following a risk-based approach, the Commission Implementing Regulation should be repealed.

Vote taken by written procedure: Favourable opinion.