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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*
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SUMMARY REPORT

A.01 Feedback on the recent work of the Expert Group on Food Contact Materials (FCM).

The Commission provided feedback on the discussions that took place in the WG on FCM of the SCPAFF that took place on 25 November 2019. The Commission services explained that at the time of the meeting a written consultation on possible amendments to Regulation 282/2008 was ongoing. During the WG the Member States were given further explanation on key elements in this amendment and had the opportunity to ask questions. Also, a discussion on the 15th amendment took place in preparation of the vote during this SC, and the elements foreseen for the 16th amendment were shortly discussed, which include RM based on the phthalates and wood opinions published by EFSA, a possible approach to biocides, and the introduction of a template based DoC (note these were erroneously listed on the WG agenda respectively as 14th and 15th amendment). The key elements of a possible measure regulating epoxy silanes ('Glymo measure') where discussed which would imply that business operators would either need to demonstrate safe use or absence of genotoxicity in an EFSA application, and which would apply to all FCM excluding plastic FCM. Feedback was given on the state of play of the evaluation of FCM, as well as the impact assessment under preparation for the possible measure on ceramic and vitreous FCM.

A.02 Discussion on the voluntary continuation of the coordinated control plan with a view to establishing the prevalence of certain substances migrating from FCM under Recommendation 2019/794.

The Commission stated that in their view the work under Recommendation 2019/794 should continue, and invited the Member States to submit further results. The recommendation would remain unmodified, but the possible addition of styrene to the monitoring programme will be discussed during the next WG. The Commission stated however that this time submission should be done by means of the EFSA submission system, and several MS strongly requested the Commission to discuss establishing an appropriate template for this purpose. The Commission services stated that the first steps are being taken to ensure EFSA's system can be used, and the data over 2019 which should be submitted by the end of February will serve as a basis for that. The matter will be discussed in detail during the next WG.

A.03 Status of "buffered vinegar".

Due to new comments received prior to the meeting, the point was not discussed.

A.04 Register of enzymes to be considered for inclusion in the Union list.

Article 17 of Regulation (EC) No 1332/2008 provides for the establishment of a Register of all food enzymes to be considered for inclusion in the Union list. A draft register was presented to the Committee for information and possible comments. Some Member States' representatives raised comments, which will be further considered before completion of this work.

A.05 Follow-up on the 2019 EFSA opinion on the evaluation of calcium lignosulphonate as an acceptable previous cargo for edible fats and oils (EFSA Journal 2019;17(12):5951).

Following the submission of new information on calcium lignosulphonate by the interested company, EFSA published on 28 November 2019 a new opinion on the evaluation of calcium lignosulphonate as an acceptable previous cargo for edible fats and oils. EFSA concluded that it would not be appropriate to add calcium lignosulphonate to the list of acceptable previous cargoes in the Annex to Regulation (EU) No 579/2014 because the information provided was still insufficient to assess the acceptability of calcium lignosulfonate as a previous cargo. The EFSA Panel specified which information is still missing. In the meanwhile the company contacted EFSA again and provided new studies, which still not address all the data gaps. Therefore a new EFSA opinion will only be requested, when EFSA, after a first reading of newly submitted information, concludes that all the required information has been delivered.

A.06 EFSA Report for 2018 on the results from the monitoring of veterinary medicinal product residues and other substances in live animals and animal products.

The Commission informed Member States that the report has now been finalised by EFSA and will be published in the following weeks. Lithuania informed that certain data from Lithuania are missing from the EFSA report due to problems with the data submission to EFSA.

A.07 Exchange of views on the draft of Commission Implementing Regulation on the performance of analytical methods for pharmacologically active substance, the interpretation of results and the methods to be used for sampling (SANTE 11188-2018).

Currently, Decision 2002/657/EC sets the requirements for the performance of analytical methods for veterinary pharmacologically active substances and the interpretation of results. The current provisions need to be updated, taking into account new scientific developments.

Decision 1998/179/EC sets detailed rules on official sampling for monitoring of certain substances and residues thereof in live animals and animal products, and also Dir. 96/23 specifies some sampling requirements. The provisions on sampling will be merged and slightly updated. The updated provisions will be included in an Implementing Regulation on the basis of Reg. 2017/625.

A majority of the delegations did not express any objection; some MSs commented on the new requirements for the validation of methods. The Commission explained that the new provisions would not result in additional costs, as transitional measures have been included, so that the new requirements will only apply to newly validated methods and will not require re-validation of existing methods. The new requirements for validations in lower concentration ranges do not entail additional analyses for validations, only a different choice of the concentrations for the existing number of calibration points. Furthermore in order to address the concerns of some Member States, it is mentioned in the draft that the future validations in lower concentration ranges only need to be performed where reasonably achievable. This leaves sufficient flexibility for Member States and prevents the need to buy new equipment.

A.08 Exchange of views and possible endorsement on the extension of the scope and of the reporting deadline for Commission Recommendation (EU) 2017/84 in the monitoring of mineral oil hydrocarbons in food and in materials and articles intended to come into contact with food.

Commission Recommendation (EU) 2017/84 on the monitoring of mineral oil hydrocarbons in food and in materials and articles, intended to come into contact with food, foresaw the data reporting deadline by 28 February 2019. As the JRC sampling and reporting guideline on mineral oil hydrocarbons only became available at the beginning of 2018, Member States agreed at the SCPAFF of 11/06/2018 on the postponement of the reporting date until 1 October 2019. After a preliminary evaluation of the data available, Member States discussed at the Working Group on Environmental and Industrial Contaminants in Food of December 2019 the possibility for the extension of the scope of the Recommendation and for a further postponement of the reporting date.

It is recommended for Member States to focus more on the following commodity categories:

- confectionery (candyfloss), foamed sugar products (marshmallow), sweet chocolate bars
- vegetable oils, such as rapeseed oil, palm oil, coconut oil, sunflower oil, intended for use in infant formula and in food for infants and young children
- marinated (pickled) fish (herrings), smoked fish (trout, carp, mackerel), canned/jarred fish in oil (anchovy, sprats…)

The Committee endorsed the extension of the scope to the following additional commodities:

- infant formula and follow-on formula
- cereal-based food for infants and young children
- milk and milk-based products
- tea and herbal tea (mainly dried products)
- food supplements (algae formula)
- millet flour
- dried herbs, vegetable powders (used for example for smoothies)

The Committee endorsed the postponement of the reporting date until 1 October 2020. The deadline is extended for the reporting of the data as well as for performing additional sampling and analyses in 2020.

A.09 Presence of mineral oil hydrocarbons (MOAH) in infant formula and follow-on formula.

The European Food Safety Authority (EFSA) concluded in its Rapid risk assessment on the possible risk for public health due to the contamination of infant formula and follow-on formula by mineral oil aromatic hydrocarbons (MOAH), that, in the absence of information on the presence or absence of 3-7 ring polycyclic aromatic compounds (3- 7 PAC), the detection of mineral oil aromatic hydrocarbons (MOAH) in food should be considered of potential concern for human health. Therefore EFSA recommended that analytical methods to identify 3-7 PAC should be routinely applied when MOAH are detected in food. A workshop with all interested parties was organised on 5 December 2019 to discuss and conclude on harmonised sample preparation and analysis as a follow-up to this recommendation from EFSA.

Competent authorities have been requested to monitor the presence of MOAH in infant formula and follow-on formula and to report these data to EFSA and the Commission. EFSA has assessed these findings on the possible risk for public health in view of determining appropriate harmonised risk management measures. EFSA presented their assessment and concluded that the presence of MOAH in infant formula has been confirmed with concentrations of MOAH in the range of 0.9 to 3.5 mg/kg and that the estimated exposure for infants and toddlers is of concern for human health, considering the possible presence of 3-7 PAC in the MOAH.

The JRC confirmed that in case the JRC guidance and the conclusions of the workshop on 5 December 2019 are complied with, quantified levels of MOAH above 2 mg/kg strongly indicate a presence of MOAH. For a more precise determination of the LOQ, a Standard Operating Procedure (SOP), specific for the matrix, has to be developed (as well reference materials). For a quantification of 3-7 PAC, more work has to be performed on the development of the method of analysis.

It is of high importance that investigations as regards the source of the presence of MOAH in infant formula and follow-on formula are intensified and if identified, remediated. Available information indicate that through a careful selection of vegetable oils to be used for the production of infant formula and follow-on formula, levels of MOAH in infant formula and follow-on formula can be reduced.

Member States agreed that a harmonised risk management approach to ensure a high level of human health protection was appropriate but requested to have more details and background on the proposed approach in order to be able to take a final positon. The Commission representative committed to provide this after the meeting and to define the common risk management approach by electronic consultation.

A.10 Exchange of views on a draft Implementing Regulation imposing conditions governing the import of food, minor food and feed originating in third countries following the accident at the Chernobyl nuclear power station.

The draft Implementing Regulation aims at continuing while alleviating the measures provided for in Council Regulation (EC) No 733/2008 that lays down maximum permitted levels of radioactivity in certain agricultural products originating in third countries affected by the Chernobyl nuclear accident, establishes specific import conditions for certain products and requires Member States to perform controls to ensure their compliance with the levels of radioactivity set out in that Regulation. Furthermore, the provisions on control have been updated in accordance with the provisions of the Official Control Regulation (EU) 2017/625.

An exchange of views took place. Member States largely agreed that it was appropriate to continue to have measures in place but requested more time for taking a final position. The Commission representative accepted this and indicated to request Member States to provide feedback in writing on the following issues:

- maximum levels as sum of caesium-134 and caesium-137 or for caesium-137 only.
- specific import conditions (official certificate, Common Health Entry document (CHED) entering the Union via Border Control Posts (BCP), prior notification, documentary and physical control at import) for wild mushrooms only or for wild mushrooms and wild fruits of the genus *Vaccinium* and derived products.
- frequency of identity and physical checks
- any other feedback.

The Commission representative indicated that, after the adoption of the draft Regulation, it will be appropriate to consider the need to update the Commission Recommendation 2003/274/Euratom of 14 April 2003 on the protection and information of the public with regard to exposure resulting from the continued radioactive caesium contamination of certain wild food products as a consequence of the accident at the Chernobyl nuclear power station.

A.11 Exchange of views on the alignment to the Official Control Regulation (Regulation EU) 2017/625) of the control provisions provided in Implementing Regulation (EU) 2016/6 imposing special conditions governing the import of feed and food originating in or consigned from Japan following the accident at the Fukushima nuclear power station.

A short exchange of view took place. No objections were raised to an alignment of the control provisions provided in Implementing Regulation (EU) 2016/6 imposing special conditions governing the import of feed and food originating in or consigned from Japan following the accident at the Fukushima nuclear power station. The Commission representative informed that the draft Implementing Regulation would be finalised once the internal consultation on the draft Implementing Regulation imposing conditions governing the import of products originating in third countries following the accident at the Chernobyl nuclear power station (see point A.10) has been completed, taking over the same control provisions, to ensure consistency.

A.12 Exchange of views on draft Regulations related to the setting of maximum levels of

- ergot sclerotia and ergot alkaloids

- pyrrolizidine alkaloids

- tropane alkaloids

- acrylamide

The Committee was informed on the status of these draft Regulations. One Member State asked if the incurred delay would have consequences for the projected date of application of the foreseen measures. Another Member States highlighted, in relation to the foreseen measures on ergot sclerotia and ergot alkaloids in rye and rye products, the need to have sufficient time to achieve lower levels. The Commission representative informed that this discussion would take place once the draft Regulations are submitted to the Committee for opinion.

The Committee was also informed of a letter from Tea and Herbal Infusions Europe as regards the need for clarification of the draft Regulation on pyrrolizidine alkaloids and tropane alkaloids with regard to powdered tea extracts (instant tea).

A.13 Exchange of views on draft implementing Regulations related to the establishment of sampling procedures and performance criteria for methods of analysis

The Committee was informed on the status of these draft Regulations.

A.14 Feedback and exchange of views on topics discussed in recent meetings of the Working groups on contaminants.

The Committee was informed about the discussion on a new implementing act, setting out the general requirements for the content of the national control plans for contaminants. Some important questions remain, which should be agreed as soon as possible, in view of the further elaboration of the implementing act:

1) Appropriateness of the inclusion of a surveillance plan for non-regulated contaminants for products placed on the market in the Member States.
2) Requirements on controls as regards food other than food of animal origin
3) Inclusion of controls of the MRLs for mercury in all foods except fish, food supplements and salt, and MRLs for copper into the control plans.
4) For food of non-animal origin, the time period for the plans could be 4 years, with a possible revision after 2 years. For products of animal origin the general requirements, which are currently included in Dir. 96/23/EC, with a longer period, should be continued

The Commission representative asked to get a clear view of the position of the Member States on these issues in view of the discussion to take place at the next meeting of the Working Group on Environmental and Industrial Contaminants on 2nd of March 2020.

<u>Discussion on maximum levels for several contaminants</u>

The Commission representative informed the Committee on ongoing discussions on possible maximum levels for tetrahydrocannabinol (THC), opium alkaloids, hydrocyanic acid, T-2 and HT-2 toxin, DON and modified forms.

Also, the risk management measures to be taken following the recent EFSA opinion on quinolizidine alkaloids are currently discussed.

As regards the follow-up to the EFSA opinion on chlorinated paraffins, the Commission representative informed the Committee that it was concluded at the working group on POPs in food (meeting of 21 January 2020) that work has to be finalised on the development of a reliable method that can be routinely applied, before taking any further action. This work on the development of a method for the analysis of chlorinated paraffins is undertaken by the European Union Reference laboratory (EURL) for POPs in feed and food in close collaboration with the National Reference Laboratories (NRLs) and is not expected to be finalised before the end of this year.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) amending the Annex to Regulation (EU) No 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards specifications for tricalcium phosphate (E 341(iii)).

The Commission received an application for the amendment of specifications for the food additive tricalcium phosphate (E 341(iii)). The current Union specifications lay down that tricalcium phosphate (E 341(iii)) is obtained from neutralisation of phosphoric acid with calcium hydroxide. The applicant requests that neutralisation with calcium carbonate is included as an alternative.

Calcium hydroxide is produced via calcination of calcium carbonate, which could be avoided if calcium carbonate was used directly as a starting material, the latter leading to the reduction of production energy needed. According to the applicant, both production processes result in the same final product, tricalcium phosphate (E 341(iii)), i.e. containing no other impurities than those specified in Regulation (EU) No 231/2012 and thus not being liable to have an effect on human health.

Therefore, the Annex to Regulation (EU) No 231/2012 should be amended, as regards the specifications for tricalcium phosphate (E 341(iii), by including calcium carbonate as an alternative to calcium hydroxide for neutralisation of phosphoric acid.

The draft Regulation presented by the Commission to the Committee concerned therefore the amendment of the Annex to Regulation (EU) No 231/2012 as a follow-up to an application.

Vote taken: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) amending Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards the use of Annatto, Bixin, Norbixin (E 160b).

Annatto, Bixin, Norbixin (E 160b) is a substance authorised as a colour in a variety of foods in accordance with Annex II to Regulation (EC) No 1333/2008. The main pigments in annatto extracts are bixin and norbixin.

The Commission received an application for the authorisation of the use of five new annatto extracts categorised as bixin- or norbixin-based, with a view to replacing the currently authorised three annatto extracts (E 160b). The application also included a request for the extension of use of E 160b into a few additional food categories. The European Food Safety Authority (EFSA) assessed this application together with the re-evaluation of the safety of E 160b, as provided by Commission Regulation (EU) No 257/2010.

EFSA concluded that the two main pigments in annatto extracts, bixin and norbixin, have different toxicological properties and therefore a different Acceptable Daily Intake (ADI). Consequently, the food additive 'Annatto, Bixin, Norbixin (E 160b)' should be deleted from the Union list of authorised food additives and two separate food additives, namely Annatto bixin (E 160b(i)) and Annatto norbixin (E 160b(ii)) should be listed instead.

Similarly, the authorised uses and use levels for the food additive Annatto, Bixin, Norbixin (E 160b) should be deleted and the authorised uses and use levels for the two new food additives Annatto bixin (E 160b(i)) and Annatto norbixin (E 160b(ii)) should be laid down, taking into account the exposure assessments for annatto bixin and annatto norbixin carried out by EFSA.

In addition EFSA concluded that five new extracts (two bixin-based and three norbixin-based) do not pose a safety concern and that specifications for them as regards each of the two new additives should be added to the Annex of Regulation (EU) No 231/2012. Similarly, the specifications from the three presently authorised E 160b extracts should be deleted.

Therefore, the draft Regulation presented by the Commission to the Committee concerned the amendment of Annexes II and III to Regulation (EC) No 1333/2008 as well as the Annex to Regulation (EU) No 231/2012 as regards the use of Annatto, Bixin, Norbixin (E 160b), in line with the conclusions and recommendations from EFSA.

Vote taken: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation authorising the placing on the market of lacto-N-tetraose under Regulation (EU) 2015/2283 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) 2017/2470.

The Commission presented the draft Commission Implementing Regulation authorising the placing on the market of lacto-N-tetraose as a novel food. The novel food which is a natural oligosaccharide constituent of human milk is intended to be used in a number of foods and in food supplements for the general population. The authorization is underpinned by a positive EFSA opinion. In the discussion, some Member States questioned the need for the authorization of this novel food in food supplements intended for infants and subsequently this particular intended use was removed from the Implementing Regulation. Thus, a revised draft Implementing Regulation authorizing lacto-N-tetraose to be used in a number of foods and in food supplements for the general population excluding infants was put forth for the Committee's opinion.

The Committee delivered its opinion with no objections.

Vote taken: Favourable opinion.

B.04 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.

The Commission presented the draft Commission Implementing Regulation (EU) correcting Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods. The measure corrects the Union list of novel foods concerning the specifications of Schizochytrium sp. (T18) oil.

The Committee delivered its opinion with no objections.

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 partially defatted chia seed (Salvia hispanica) powders as novel foods under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470.

The Commission presented the draft Commission Implementing Regulation (EU) authorising the placing on the market of partially defatted chia seed (Salvia hispanica) powders as novel foods under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470. The measure authorises placing on the market of partially defatted chia seed (Salvia hispanica) powders as novel foods. The novel foods are intended to be used in a number of foods for the general population. This draft is underpinned by a positive EFSA opinion.

The Committee delivered its opinion with no objections.

Vote taken: Favourable opinion.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation authorising the change in the specifications of spermidine rich wheat germ extract 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 the draft Commission Implementing Regulation authorising the change of the specifications of the novel food spermidine rich wheat germ extract (*Triticum* aestivum) 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 change in the levels of cadaverine in the authorised novel food from the current <0.1 μg/g to the level of ≤16.0 μg/g to account for the natural variation in the levels of the cadaverine in the wheat germ.

The Committee delivered its opinion with no objections.

Vote taken: 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 3-monochloropropane diol (3-MCPD), 3-MCPD fatty acid esters and glycidyl fatty acid esters in certain foods.

The draft Commission Regulation provides for the establishment of maximum levels of 3-MCPD esters in vegetable oils, fish oil, infant formula, follow-on formula, young child formula and foods for special medical purposes intended for infants and young children. In addition to the existing maximum levels for glycidyl esters in vegetable oils and foods for infants and young children, the draft Regulation provides for the establishment of maximum levels for glycidyl esters in fish oil and young child formula.

An exchange of views took place.

A delegation requested to provide explicitly for a review within two years after the entry into application of the proposed maximum levels for 3-MCPD-esters in foods for infants and young children. No objection was raised to this request.

One delegation indicated not to be in favour of the establishment of two different levels for 3-MCPD esters for different vegetable oils, but acknowledged that this concern has been extensively discussed in the working group.

Vote taken: Favourable opinion.

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Regulation (EC) 1881/2006 as regards maximum levels of polycyclic aromatic hydrocarbons (PAHs) in traditionally smoked meat and meat products and traditionally smoked fish and fishery products and establishing a maximum level of PAHs in powders of food of plant origin used for the preparation of beverages.

A temporary derogation from the application of the lower maximum levels for PAHs as of 1 September 2014 was granted to several Member States for the placing on their market of traditionally smoked meat and smoked meat products and/or smoked fish and smoked fishery products, smoked in their territory and intended for consumption in their territory. The maximum levels applicable before 1 September 2014 continued to apply to those smoked products. The derogation covered generally all smoked meat and smoked meat products and/or smoked fish and smoked fishery products, without indication of the specific names of foodstuffs.

Following a detailed assessment of the information provided by the concerned Member States on the feasibility to lower the levels of PAHs by good smoking practices without losing typical organoleptic characteristics, it was concluded that the lower PAH levels were not achievable by changing smoking practices within the limits of what is economically feasible and possible without losing typical organoleptic characteristics in certain traditionally smoked meat and smoked meat products in Ireland, Spain, Croatia, Cyprus, Latvia, Poland, Portugal, Slovak Republic, Finland, and Sweden and in certain traditionally smoked fish and smoked fishery products in Latvia, Finland and Sweden. Therefore a derogation for local production and consumption without a time limit is proposed for certain traditionally smoked meat and smoked meat products, smoked fish and smoked fishery products in the Member States concerned.

The draft Regulation provides furthermore for the establishment of a maximum level for PAHs in certain powders of food of plant origin, used for the preparation of beverages.

An exchange of views took place. A delegation indicated that it would be appropriate to limit the transition period for the application of the maximum levels for powders of food of plant origin placed on the market before the entry into application to 6 months in order to be consistent with the approach taken for other genotoxic carcinogenic contaminants. No objection was raised to this suggestion.

Vote taken: Favourable opinion.

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (15th Amendment).

The Commission briefly explained the main elements of this amendment, which include the authorisation or change of 5 substances on Annex I, the update of Annex II to the Regulation, the addition of a procedure to test appliances and food processing equipment, and the requirement that the migration in subsequent specific migration tests for repeat use articles shall not increase from the first to the third tests. The ensuing discussion focussed mostly at the LOD which is being explicitly defined for some substances subject to and ND limit as specified in Article 11(4) of the Regulation. MS consider that these must be lowered further given the capabilities of modern testing equipment. The Commission services said this is agreed and the intention of the present policy, however, this can only be done if the EURL-FCM is able to confirm on the basis of a proficiency test that such a level can be achieved. The Commission will actively communicate to the industry that it is the intention that these limits will be lowered over the next few years, and ask the EURL to work on this. This matter will be further discussed during the next WG.

Vote taken: Favourable opinion.