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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 discussions during the Expert Groups on Food Contact Materials on 1-2 July 2019 and 10 September 2019.

The Commission provided feedback on two past meetings of the Working Group on food contact materials (FCM), which took place on 1-2 July and 10 September 2019.

The Working Group in July addressed various matters regarding the Official Controls Regulation (Regulation (EU) 2017/625), in particular the registration of operators (Art 10(2)), and the use of methods by the Official Control Laboratories (Art 34 and 37). Other points included a presentation on the work of the cross sector group by Plastics Europe, and short points on cyclic oligomers, the monitoring recommendation and Beeswax.

The Working Group in September specifically addressed the future needs for the Better Training for Safer Food (BTSF) programme. Prof. M. Zhong, from the National Reference Laboratory for FCM, Guangdong, gave a presentation about FCM in China. Also, a short feedback from a meeting with industry on 6 September was presented.

Common points:

- The 14th amendment of the FCM Plastics Regulation was discussed, as a new version is being developed. Member States will be provided with it ahead of the standing committee where it will be put for vote.
- A discussion on a measure for Glymo took place; this would regulate epoxy silanes either on the basis of their toxicity if Specific Migration Limit can be derived, or on the basis of absence of migration in a specific use scenario.
- Feedback on the recycling of plastics was given; Regulation (EC) no 282/2008 will be amended, so as to address the transition approach, to clarify various obligations, and to deal with plastics not in the scope of the Regulation at present.
- Feedback on the evaluation of the FCM legislation was given. The study is now being completed, a report will follow. The Commission services will prepare a staff working document to be finalised by mid-2020.

A.02 Feedback on the exchange of views regarding titanium dioxide when used as a food additive (E171), which took place at the meeting of the Working Party of Governmental Experts on Additives of 16 September 2019.

The Commission services provided feedback on the discussion on titanium dioxide (E171) which took place at the meeting of the Working Party of Governmental Experts on Additives of 16 September 2019.

At that meeting and in the light of the most recent EFSA opinion on the characterisation of E171[1], Member States were asked to answer questions related to the follow-up to be given to the French notification of a temporary suspension for one year, renewable; the possibility of setting up alternative risk management measures at the EU level; and the possible economic impact restrictions of use for E171 would have on their market.

Member States reiterated their previous positions expressed at the Committee meeting of 13 May 2019, and stressed their strong preference for an EU-wide approach and for the role of EFSA as the reference point for the scientific evaluation and for any possible follow-up risk management measures.

The Commission clarified that several Member States asked for a swift follow-up to EFSA's latest opinion, with an EU-wide improved characterisation of the substances to be used as food additive. Most Member States were of the view that one should wait for the result of the ongoing studies, due by July 2020, and for a final opinion by EFSA before a decision on E171 can be taken. Some Member States would eventually be ready to start discussing amendments of the conditions of use, implying a dialogue with the industry, and thus possibly limit the exposure to E171.

Very few precise data on the economic impact were presented on 16 September, however, it was stressed that the impact would be very significant, especially on food supplements, confectionary and bakery products which would affect primarily SMEs, and that a sufficient transitional period should be envisaged if restrictive measures were to be considered.

A short exchange of views followed which reconfirmed the spirit of the discussions which took place in the Working Group.

[1] http://www.efsa.europa.eu/en/efsajournal/pub/5760

A.03 Approval of the 2019 Member States' plans for monitoring of residues in accordance with Directive 96/23/EC.

The Commission informed that the Member States' residue monitoring plans for animals and animal products had been evaluated by DG SANTE as foreseen by Directive 96/23/EC. This evaluation includes the review of the plans by the European Union Reference Laboratories. The Commission recommended the approval of all 28 Member States' residue monitoring plans for 2019.

Member States raised no comments during the meeting. The Commission informed that it will approve the plans through the residue application electronically, if no further comments are received from Member States within 10 days, as foreseen in Article 8 of Directive 96/23/EC.

A.04 Draft Commission Recommendation on the monitoring of Alternaria toxins in food. Exchange of views and possible endorsement.

The European Food Safety Authority (EFSA) Panel on Contaminants in the Food Chain (CONTAM) adopted in 2011 a scientific opinion on the risks for animal and public health related to the presence of *Alternaria* in food.

EFSA published also more recently a scientific report on the dietary exposure assessment to *Alternaria* toxins in the European population. The main *Alternaria* toxins of concern are alternariol (AOH) and alternariol monomethyl ether (AME) and tenuazonic acid (TeA).

EFSA recommended that more occurrence data are generated on the presence *Alternaria* toxins in relevant food commodities.

The application of good agricultural practices (GAP), good storage and transport conditions and good manufacturing practices (GMP) can reduce or prevent the presence of *Alternaria* toxins in food.

Therefore, it is necessary to obtain more information on the different factors which lead to relative high levels of *Alternaria* toxins in certain foodstuffs in order to be able to identify the measures to be taken to avoid or to reduce the presence of *Alternaria* toxins in these foodstuffs. Indicative levels above which investigations on these factors should be carried out are proposed in the draft Recommendation.

The Committee endorsed the draft Recommendation

A.05 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. Exchange of views and continuation of the discussion held at the meeting of the Committee on 27/06/2009.

Council Regulation (EC) No 733/2008 of 15 July 2008 on the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power station expires on 31 March 2020.

The Commission Legal Service advised to prolong the measures, if needed, in the form of a Commission Implementing Regulation on the basis of Article 53 (1) (b) (ii) of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

Therefore, a draft Commission 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 is currently under discussion to extend the post-Chernobyl measures beyond 31 March 2020 for another period of 10 years.

An exchange of views took place on the conditions to be imposed on the import of food and feed originating in third countries.

A.06 Feedback and exchange of views on topics discussed in recent meetings of the Working Groups on contaminants.

The Commission informed the Committee on the current status of the discussions on certain topics

- **maximum levels for pyrrolizidine alkaloids:** technical discussions on the maximum levels are finalised. Further discussion on the aspect of co-elution will be discussed at the EURL/NRL workshop on Mycotoxins and Plant toxins early October 2019.
- **maximum levels for ergot and ergot alkaloids :** technical discussions on the maximum levels finalised
- **maximum levels for tropane alkaloids :** technical discussions close to finalisation (specific higher maximum level for herbal infusions exclusively composed of anise fruits and/or fennel fruits under consideration).
- **maximum levels for opium alkaloids:** maximum level for morphine equivalents **(**morphine + 0.2 codeine) in poppy seeds and bakery products containing poppy seeds were discussed.
- **sampling frequency for control** of **aflatoxins in almonds from US:** the return to the sampling frequency as provided by Regulation (EU) 2015/949 is confirmed (after a temporary increased vigilance since April 2018), based on the fact that since 1st October 2018 the situation has improved with a very low rate of non-compliance.
- **mineral oil hydrocarbons:** The deadline of EFSA for data submission (1 October) will be awaited to verify with EFSA if sufficient data have been provided. If not, another extension of the monitoring submission deadline might need to be considered and submitted for endorsement by the Standing Committee. In any case, Member States should not stop collecting and sending the data to EFSA, as part of the data collection for 2020.

  Member States were encouraged to submit all available data to EFSA by 1st October or at least inform EFSA (before the deadline) that they will submit additional data, in an agreed timeline.
- **possible EU legislation on controls on levels of contaminants in food:** Regulation 2017/625 lays down rules for the performance of official controls and other official activities by the competent authorities of the Member States for the verification of compliance with the Union legislation in the area of food and food safety. This Regulation repeals the Council Directive 96/23/EC, which covers control plans for pesticide residues, residues of pharmacologically active substances and contaminants in animals and in food of animal origin.

A general questionnaire was sent to the Member to gather information as a basis for future discussion.

Taking into account the replies received, consideration should be given to elaborate legislation on control of contaminants in food, providing the legal basis for a risk-based control plan for Union production, surveillance plan for Union production and risk-based control plan for third countries imports. Further discussion shall take place during next meetings of the different working groups on contaminants.

- **update of pamphlets for the reduction of acrylamide**

  The changes to the pamphlets following comments from a Member State were agreed.

B.01[2] Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the extension of the use of polysorbates (E 432-436) in beverages.

Polysorbates (E 432-436) are substances authorised for use as food additives in a wide variety of foods in accordance with Annex II to Regulation (EC) No 1333/2008.

The Commission received an application for the authorisation of the use of polysorbate 65 (E 436) as an anti-foaming agent in several types of beverages.

The European Food Safety Authority re-evaluated the safety of polysorbates (E 432-436) and concluded that the exposure estimates do not exceed the acceptable daily intake (ADI) of 25 mg/kg body weight/day in the refined non-brand-loyal scenario for all age groups.

The impact on the overall exposure from the extended use of polysorbate 65 (E 436) at the maximum level of 10 mg/kg in the food categories 14.1.4 'Flavoured drinks', 14.2.3 'Cider and perry', 14.2.4 'Fruit wine and made wine' and 14.2.8 'Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15% of alcohol' in Part E of Annex II to Regulation (EC) No 1333/2008 is negligible.

The draft Regulation presented by the Commission to the Committee concerned therefore the amendment of Annex II to Regulation (EC) No 1333/2008 as a follow-up to an application.

The draft was discussed.

Vote Postponed

[2] The Committee was not asked for an opinion on the drafts falling within the 'Regulatory procedure with scrutiny' due to the procedural reasons linked to the transition between the current Commission (2014-2019) and the new Commission (2019-2024). The corresponding votes were due to be taken at a later Committee meeting.

B.02[2] **Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the extension of the use citric acid (E 330) in cocoa and chocolate products.**

Citric acid (E 330) is a food additive authorised in a variety of foods in accordance with Annex II to Regulation (EC) No 1333/2008.

The Commission received an application for the modification of the conditions of use of citric acid (E 330) contained in food category 05.1 'Cocoa and Chocolate products as covered by Directive 2000/36/EC', by increasing its maximum level of use to 10 000 mg/kg for milk chocolate.

Citric acid (E 330), when used as a stabiliser in cocoa mass containing high levels of polyphenols, lowers pH and reacts with a part of polyphenols intensifying cocoa mass colour into characteristic pink shades accompanied by a berry-fruit sour taste which is achievable with the maximum level of 10 000 mg/kg.

The safety of citric acid (E 330) was evaluated by the Scientific Committee for Food, which established its acceptable daily intake as 'not specified'. The term 'not specified' is used when, on the basis of the available toxicological, biochemical and clinical data, the total daily intake of the substance, arising from its natural occurrence and its present use or uses in food at the levels necessary to achieve the desired technological effect, will not present a hazard to health.

Therefore, it is appropriate to authorise the use of citric acid (E 330) in milk chocolate at 10 000 mg/kg.

The draft Regulation presented by the Commission to the Committee concerned therefore the amendment of Annex II to Regulation (EC) No 1333/2008 as a follow-up to an application.

The draft was discussed.

Vote Postponed

B.03[2] **Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the conditions of the use of soybean hemicellulose (E 426).**

Soybean hemicellulose (E 426) is a food additive authorised in a variety of foods in accordance with Annex II to Regulation (EC) No 1333/2008.

The Commission received an application for the extension of use of soybean hemicellulose (E 426) as a stabiliser in flavoured fermented milk products and flavoured drinks to prevent an agglomeration and precipitation of proteins and phase separation under acidic conditions.

The European Food Safety Authority re-evaluated the safety of soybean hemicellulose (E 426) and concluded that it is very unlikely that there is a safety concern from the current use of soybean hemicellulose (E 426) as a food additive, and that there is no need for a numerical acceptable daily intake (ADI). Such conclusion is used for substances of a very low safety concern and only if there is reliable information for both exposure and toxicity and there is a low probability of adverse health effects in humans at doses that do not induce nutritional imbalance in animals.

Therefore, it is appropriate to include soybean hemicellulose (E 426) in Group I of Part C of Annex II to Regulation (EC) No 1333/2008 that also covers the requested extension of use.

The draft Regulation presented by the Commission to the Committee concerned therefore the amendment of Annexes I and II to Regulation (EC) No 1333/2008 as a follow-up to an application.

The draft was discussed.

One Member State stressed the importance of ensuring that an adequate information about the presence of potentially allergenic proteins in soybean hemicellulose (E 426) is provided to the consumer and expressed its regret that the relevant recital, which was included in the first version of the draft, was not in the draft presented to the Committee.

The Commission clarified that, as the recital was not reflected in the Annex of the draft and as the matter described in the recital was not subject to the draft under consideration, it was deleted following the Commission's internal consultation procedure. However, this deletion does not in any way question the fact that soybeans and products thereof listed in Annex II to Regulation (EU) No 1169/2011 of the European Parliament and of the Council are among substances or products causing allergies or intolerances whose indication, with the exception of certain specified products, shall be mandatory. This obligation also applies to soybean hemicellulose (E 426).

Vote Postponed

B.04[2] **Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of sorbic acid (E 200) in liquid colour preparations for the decorative colouring of egg shells.**

The Commission received an application for the modification of the conditions of use of sorbic acid (E 200) in liquid colour preparations for sale to the final consumer for the decorative colouring of egg shells. Pursuant to Part 2 of Annex III to Regulation (EC) No 1333/2008, sorbic acid (E 200) is an already authorised food additive in colour preparations at a maximum level of 1 500 mg/kg in the preparation. The application shows that a higher level of sorbic acid (E 200) (2 500 mg/kg in the preparation) is needed to consistently ensure appropriate preservation, and consequently microbiological safety, of these specific liquid colour preparations.

EFSA recently established a new group ADI for sorbic acid (E 200) and potassium sorbate (E 202) of 11 mg sorbic acid/kg bw per day, and concluded that the currently authorised uses of sorbic acid (E 200) and potassium sorbate (E 202) do not lead to an exceedance of the ADI. It results from the tests carried out by the applicant that the migration of sorbic acid (E 200) from the egg shell to the edible part of the egg is below the level of detection. Consequently, the requested higher level of sorbic acid (E 200) would not lead to an increase of the exposure of consumers to sorbic acid (E 200) and is not of safety concern.

Therefore, it is appropriate to authorise the use of sorbic acid (E 200) as a preservative in liquid colour preparations for the sale to the final consumer for the decorative colouring of egg shells at the maximum level of 2 500 mg/kg in the preparation.

The draft was discussed.

Vote Postponed

B.05[2] **Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of polyglycerol polyricinoleate (E 476) in liquid vegetable oil emulsions.**

The Commission received an application for the authorisation of the use of polyglycerol polyricinoleate (PGPR, E 476) as an emulsifier in liquid vegetable oil emulsions for sale to the final consumer, having a fat content of 70 % or less.

PGPR (E 476) is a water-in-oil emulsifier capable of forming very stable oil emulsions with high water content. In studies carried out by the applicant, comparing the effectiveness of different emulsifiers for the production of liquid vegetable oil emulsions with reduced fat content, PGPR (E 476) gave the best results both in terms of physical as well as organoleptic properties of the obtained product. The emulsion can be used in the same way as vegetable oils for the preparation of cold and hot dishes. However, the emulsion has a lower fat content (70 % or less), and therefore a lower caloric content than the vegetable oil used for its production. The level of use of PGPR (E 476) needed to achieve the intended technological function was 4 000 mg/kg.

In 2017 EFSA re-evaluated the safety of PGPR (E 476) and concluded that the authorised uses would not lead to an exceedance of the ADI. The applicant has shown that the requested new use of PGPR (E 476) does not lead to an exceedance of the ADI and it is therefore of safety concern.

Therefore, it is appropriate to authorise the use of PGPR (E 476) as an emulsifier in liquid vegetable oil emulsions for sale to the final consumer, having a fat content of 70 % or less (food category 02.2.2).

The draft was discussed.

Vote Postponed

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation authorising the placing on the market of 2'-Fucosyllactose/Difucosyllactose mixture 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 placing on the market of 2'-Fucosyllactose/Difucosyllactose mixture as a novel food. The measure authorises the use of the novel food in unflavoured pasteurised and unflavoured sterilised milk products, flavoured and unflavoured fermented milk based products including heat-treated products, cereal bars, flavoured drink beverages, infant formula and follow-on formula and processed cereal-based food and baby food for infants and young children, foods for special medical purposes, and total diet replacement foods for weight control as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council, and in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council intended for the general population, excluding infants.

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 Implementing Regulation authorising the placing on the market of Phenylcapsaicin 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 placing on the market of Phenylcapsaicin as a novel food. The measure authorises the use of the novel food in foods for special medical purposes as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council excluding those intended for infants young children and children under the age of 11 years, and in food supplements as defined in Directive No 2002/46/EC of the European Parliament and of the Council intended for the general population above the age of 11 years.

One Member State abstained as it considered that the novel food offered no nutritional benefit.

Vote taken: Favourable opinion.

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation authorising an extension of use of chia seeds (Salvia hispanica) as a novel food and the change of the specific labelling requirements of chia seeds (Salvia hispanica) under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470.

The Committee was informed that the draft is still following the Commission's internal validation process. Therefore, the draft will be presented for discussion and vote at the next Committee meeting, due to take place on 18 November 2019.

Vote Postponed

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) amending 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 existing measures have been reviewed taking into account more than 100,000 occurrence data on radioactivity in feed and food other than beef and more than 534,000 occurrence data on radioactivity in beef, provided by the Japanese authorities concerning the seventh and eight growing season (January 2017 to December 2018) after the accident.

Taking into account these control results, the existing measures can be significantly alleviated. On the request of a delegation, information was provided on the status of the contaminated cooling water in Japan.

One Member State could not support the draft Regulation as it is of the opinion that the measure is not needed anymore for the protection of public health, given the levels of contamination found in feed and food exported from Japan into the EU. Another delegation shared this view, but supported the draft measure.

The Committee expressed a favourable opinion.

Vote taken: Favourable opinion.

B.10 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.

The draft Regulation restricts the scope of the derogation to these traditionally smoked meat and meat products and fish and fish products, for which the stricter levels are not achievable despite the efforts to reduce the presence of PAHs. In addition, it is foreseen to set a maximum level for plant powders used for beverages (e.g. smoothies) in which in certain cases very high levels of PAHs have been found due to bad drying practices.

Following the public consultation, 9 comments were received. Three from stakeholder associations, 5 from EU citizens and one from an NGO. The comments received were reported to the Committee in detail. The Committee agreed that no changes are needed to the draft Regulation following the public consultation.

One Member State indicated not to support the measure given that derogations granted to some Member States are not specific enough.

The vote was not taken for procedural reasons linked to the transitional arrangements taken in view of the upcoming change of Commission.

Vote Postponed

B.11 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Regulation (EC) 1881/2006 as regards maximum levels of perchlorate in certain foods.

This draft Regulation establishes maximum levels for perchlorate in foodstuffs which contain significant levels of perchlorate and which contribute significantly to the human exposure or which are of relevance for the exposure of vulnerable groups of the population such as infants and young children.

No comments were made.

The vote was not taken for procedural reasons linked to the transitional arrangements taken in view of the upcoming change of Commission.

Vote Postponed

B.12 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.

This draft Regulation establishes maximum levels for glycidyl fatty acid esters in fish oils and oils from other marine organisms, in young child formula and maximum levels for 3-MCPD esters in vegetable oils, fish oils and oils from other marine organisms, in infant formula, follow on formula and young child formula.

One delegation indicated not to be in favour of a split level for different vegetable oils. No other comments were made

The vote was not taken for procedural reasons linked to the transitional arrangements taken in view of the upcoming change of Commission.

Vote Postponed

B.13 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Regulation (EC) No 333/2007 as regards the analysis of 3-monochloropropane diol (3-MCPD) fatty acid esters, glycidyl fatty acid esters, acrylamide and perchlorate.

The draft Regulation provides for performance criteria to comply with the methods of analysis to be used for the control of the presence 3-monochloropropane diol (3-MCPD) fatty acid esters, glycidyl fatty acid esters, acrylamide and perchlorate.

One delegation indicated not to support the measure as their official laboratory needs more time to be able to comply with the performance criteria.

Vote taken: Favourable opinion.

B.14 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) correcting certain language versions of Regulation (EC) No 124/2009 setting maximum levels for the presence of coccidiostats or histomonostats in food resulting from the unavoidable carry-over of these substances in non-target feed (language versions to be corrected: BG, LT and HR).

A correction is needed in the BG, LT and HR version of Regulation (EC) 124/2009. Given that the nature of the error is assessed to be substantial (unit in which the maximum level is expressed), the error needs to be corrected with a correcting act following the same regulatory procedure as the act to be corrected, i.e. regulatory procedure with scrutiny.

No comments were made

The vote was not taken for procedural reasons linked to the transitional arrangements taken in view of the upcoming change of Commission.

Vote Postponed

M.01 RASFF notification on the residual presence of a genetically modified organism in a food enzyme from Denmark.

The Commission informed the Committee on the RASFF notification ref. 2019.3332. It stressed the importance and obligations of Member States as regards the enforcement of the legislation, in particular Regulation (EC) No 1829/2003. The Commission requested that Denmark follows-up with this notification and reports at the next meeting of the Committee or at the next meeting of the Working Party of Governmental Experts on Enzymes.