SUMMARY REPORT OF THE
STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED
HELD IN BRUSSELS ON 17 APRIL 2018
(Section Novel Food and Toxicological Safety of the Food Chain)

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A.01 Commission Expert Group on Residues of Veterinary Medicines: nomination of permanent representatives by the PAFF Committee.

The Commission informed on the establishment of the Commission Expert Group on Residues of Veterinary Medicines and asked the Member States to nominate permanent representatives for this Group by 19 April 2018. The first meeting will take place on 4 May 2018. In this meeting, discussions will take place on a Commission Delegated Regulation concerning the conditions to be respected by animals and goods entering the Union from third countries and a Commission Delegated Regulation on the measures to be taken by the competent authorities for specific cases of non-compliance or suspicion thereof of animals and goods from the EU or third countries related to veterinary medicinal products and their residues.

A.02 Feedback from the Working group on Industrial and Environmental contaminants.

Acrylamide

Guidance

The guidance for the implementation of Commission Regulation (EU) 2017/2158 of 20 November 2017 establishing mitigation measures and benchmark levels for the reduction of the presence of acrylamide in food was presented and discussed.

The guidance relates to the scope (foods covered by the Regulation), the categorisation of food businesses, benchmark levels (meaning and guidance as regards the application for specific foods), application of mitigation measures, sampling and analysis, record keeping, colour guides. The guidance document has been extensively discussed at the Working Group meeting on 27 March 2018 and has been submitted for information and comments to the stakeholder organisations. The document presented at the Committee takes into account the outcome of the discussions at the meeting on 27 March 2018 and the comments received from stakeholders and Member States prior to this meeting.

Several delegations welcomed the document but indicated that further fine-tuning would still be needed. The Commission informed about the organisation of another Working Group meeting to discuss the remaining issues in view of the finalisation of the guidance at the next meeting of the Committee on 11 June 2018.
Replacement of Commission Recommendation 2013/647/EU

On request of a delegation, the Commission clarified that the indicative levels for acrylamide provided for in Commission Recommendation 2013/647/EU are superseded by the benchmark levels provided for in Commission Regulation (EU) 2017/2158, even if Commission Recommendation 2013/647/EU has not yet been repealed.

It is foreseen to replace the latter Recommendation by a new Recommendation on the monitoring of acrylamide in foods not covered by Regulation (EU) 2017/2158, such as vegetable crisps, roasted nuts, roasted oilseeds, dried fruit, roasted cocoa beans, certain potato products, certain bakery products and certain cereal products.

Update of Commission Regulation (EC) No 333/2007 and maximum levels

Discussions are ongoing on an amendment to Regulation (EC) No 333/2007 as regards performance criteria for the analysis of acrylamide (and other process contaminants) and discussions on the setting of maximum levels for certain foods has been initiated.

PAHs in traditionally smoked meat and meat products and fish and fish products

The Commission informed the Committee of the proposed amendment to paragraphs 6 and 7 of Article 7 of Commission Regulation (EC) No 1881/2006 as regards the maximum levels for PAHs in traditionally smoked meat and meat products and fish and fish products. No comments were made. The Commission confirmed to have received the comments from the Slovak Republic in writing.

In addition, a maximum level for PAHs in plant powders used for the preparation of smoothies is foreseen and an amendment to Regulation (EC) No 333/2007 is foreseen as regards performance criteria for the analysis of PAHs.

Mercury

The Commission gave an update on the discussions, which took place in the Working Group Meeting on Industrial and Environmental contaminants of 27 March. A Member State considered it necessary to include the requirement on reporting on the effectiveness of the consumption advice for fish on a mandatory basis. However, the Commission considered that such reporting would be mainly of relevance for countries with high consumption of predatory fish and that therefore this reporting should be done on a voluntary basis.

3-MCPD esters

Maximum levels for 3-MCPD esters are being discussed for the same food groups as those for which maximum levels for glycidyl esters are already in application. Maximum levels for glycidyl esters and MCPD esters in fish oils for human consumption (food supplements) are also being discussed.

Furthermore, the necessity to establish in the future maximum levels for glycidyl esters and 3-MCPD esters in baby food and processed cereal-based food for infants and young children and for 3-MCPD (esters) in other foods is being discussed.

Regulation (EC) No 333/2007 has also to be amended as regards performance criteria for the analysis of glycidyl esters and 3-MCPD esters.

Other issues
a) 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.

The Commission updated the Member States on the expected timelines for the guidance on sampling, reporting and analytical methods for mineral oil hydrocarbons in food and food contact materials. In view of the delays in the publication of these guidelines, the Commission enquired whether an extension of the reporting deadline would be required and it asked Member States to inform the Commission by 27 April on their intention to submit data and to collect additional samples and data in 2019.

b) An update on the ongoing discussions as regards perchlorate and furan was provided.

A.03 Feedback from the Working group on Agricultural contaminants.

Pyrrolizidine alkaloids

The Committee agreed that possible regulatory measures as regards the presence of pyrrolizidine alkaloids in tea, herbal infusions, food supplements and honey are to be based on the sum of the following 21 pyrrolizidine alkaloids (17 in accordance with the EFSA recommendation and 4 heliotrine type pyrrolizidine alkaloids, given the very high levels of these pyrrolizidine alkaloids in certain herbs/herbal mixtures and certain teas/herbal infusions):

- Intermedine/lycopsamine, intermedine-N-oxide/lycopsamine-N-oxide;
- Senecionine/senecivernine, senecionine-N-oxide/senecivernine-N-oxide;
- Seneciphylline, seneciphylpine-N-oxide;
- Retrorsine, retrorsine-N-oxide;
- Echimidine, echimidine-N-oxide;
- Lasiocarpine, lasiocarpine-N-oxide;
- Senkirkine;
- Europine, europine-N-oxide;
- Heliotrine and heliotrine-N-oxide.

It was also discussed that possible maximum levels are to be set as lower bound with strict requirements as regards the Limit of Quantification (LOQ) to be achieved. The European Reference Laboratory (EURL) on mycotoxins and plant toxins shall be consulted on what LOQ is reasonably achievable by NRLs and well-equipped official laboratories.

Furthermore, the possible setting of maximum levels should be considered for following foodstuffs (in order of priority/importance):

- tea and herbal infusions, and tea for infants and young children (products as marketed – dry matter or liquid);
- herbal food supplements (differentiation between food supplements derived on purpose from pyrrolizidine alkaloid containing plants and food supplements accidentally contaminated with pyrrolizidine alkaloid containing plants) and herbs;
- honey (retail and bulk) and pollen-based food supplements.
**Ergot alkaloids**

Possible maximum levels are to be set for the sum of the following 12 ergot alkaloids: ergometrine, ergosine, ergocornine, ergotamine, ergocristine, ergocryptine and their respective inine forms as lower bound, with strict requirements as regards the LOQ to be achieved. The EURL on mycotoxins and plant toxins shall be consulted on what LOQ is reasonably achievable by NRLs and well-equipped official laboratories. EURL has also been requested to provide information on the reliability of screening methods for the presence of ergot alkaloids.

For the time being, possible maximum levels for certain cereal milling products are considered.

**Erucic acid and ochratoxin A**

The Committee was informed of the possible maximum levels for erucic acid and ochratoxin A that were put to a targeted stakeholder consultation with 14 May 2018 as a deadline for comments.

**Review of Regulation (EU) No 884/2014**

The amendment of Regulation (EU) No 884/2014 relates to following issues:

- modification of competent authorities (India, Ethiopia and Brazil) entitled to sign health certificate;
- possible modification to Article 9 to clarify the issues related to the role of custom authorities and to remove inconsistencies;
- changes to the Annex;
- a possible increased frequency of control of aflatoxins in dried figs from Turkey (from 10 to 20 %);
- transfer of following entries from Regulation (EC) No 669/2009 to Regulation (EU) No 884/2014 : groundnuts from Bolivia (control frequency 50 %), groundnuts from Gambia (control frequency 50 %), groundnuts from Madagascar (control frequency 50 %), groundnuts from Senegal (control frequency 50 %), groundnuts from Sudan (control frequency 50 %), watermelon seeds from Sierra Leone (control frequency 50 %).

Furthermore, the Committee was informed that, as regards the presence of aflatoxins in peanuts from the US, the situation has significantly improved since 2016, but vigilance needs to be maintained. The Commission services shall continue to closely monitor the situation.

Following the recent increased number of RASFF notifications as regards the presence of aflatoxins in almonds from US and the additional clarifications and commitments provided by the Almond Board of California, it is appropriate to be vigilant; therefore the sampling frequency of < 1 % provided for in Regulation (EU) 2015/949 is temporarily not applicable. The Commission services shall continue to closely monitor the situation.

**Other issues**

The Committee was also informed on :

- the ongoing discussion in the working group on Alternaria toxins, citrinine (lowering of maximum level in food supplements based on rice fermented
with red yeast *Monascus purpureus* from 2000 µg/kg to 500 µg/kg) and tropane alkaloids;

- the mycotoxin forum on 14-15 May 2018;
- the intention of the Commission services to request EFSA to perform a comprehensive risk assessment on aflatoxins;
- the ongoing discussions in Council and European Parliament as regards hydrocyanic acid and ethyl carbamate in stone fruit spirit in the frame of replacement of Spirit Drinks Regulation (EC) No 110/2008 was provided.

Finally, the attention of the Committee was drawn to the recent finding of high levels of hydrocyanic acid in apricot kernels on the EU market and the consequent adverse health effects. Therefore, reinforced control on the presence of hydrocyanic acid in apricot kernels is of major importance for the protection of public health.

**A.04 Exchange of views on a FR note on titanium dioxide.**

France presented a note sent to the European Commission on 15 February 2018, which requests the adoption of interim protective measures provided for by Article 53 of Regulation (EC) No 178/2002, in particular measures for suspension of the placing on the market or use of the food additive titanium dioxide (E171) in all food of European origin and measures for suspension of imports of all food containing that additive from third countries. France based this request on the fact that in the re-evaluation of the safety of titanium dioxide (E 171) as a food additive (Scientific Opinion published on 14 September 2016) EFSA was unable to reach a definitive conclusion on the reproductive and developmental toxicity endpoint and therefore EFSA did not establish an acceptable daily intake (ADI). France also mentioned as justification for this request four studies on the potential toxicity of titanium dioxide used as a food additive (E 171), which were published after the adoption of EFSA’s Opinion.

The Commission requested EFSA on 22 March 2018 to evaluate those studies and to indicate whether they would merit re-opening the existing Opinion of EFSA related to the safety of titanium dioxide (E 171) as a food additive. Therefore, the Commission invited EFSA to attend this meeting to provide an update on its activities on titanium dioxide (E 171).

In its presentation, EFSA described the main conclusions and recommendations of its recent scientific opinion on the re-evaluation of the safety of E 171 as a food additive. EFSA clarified that even though no ADI was established, the margin of safety (MoS) calculated was not considered of concern. EFSA acknowledged that on 30 January 2017 the Commission published a call for scientific and technical data on titanium dioxide (E 171) addressing data needs identified by EFSA in the re-evaluation scientific opinion. As a consequence of that call, new reproductive toxicity data will become available in August 2019, which should enable EFSA to establish an ADI for the food additive titanium dioxide (E 171). Data on particle size and particle size distribution for inclusion in the specification of E 171 will become available by the end of June 2018.

EFSA reported on its collaboration with the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) in the 1st quarter 2017 for the evaluation of the possible impact of a publication on titanium dioxide of Bettini *et al.* (Jan 2017,
INRA) on the safety of E 171. This is one of the studies cited in the French note. EFSA agreed with the ANSES’ conclusions that there was no need to reopen the EFSA opinion on E 171 on the basis of this study.

EFSA also reported on its collaboration with ECHA in the second quarter 2017. EFSA clarified that even though titanium dioxide has been classified as a “substance suspected of causing cancer” (category 2) via inhalation, there is no concern about carcinogenicity via oral or dermal administration.

As for the request from the Commission to EFSA of 22 March 2018 to evaluate the four new studies potential toxicity of titanium dioxide cited in the French note, EFSA intends to adopt a scientific opinion no later than June 2018. The scientific opinion will be published and delivered about one month later.

This scientific opinion will help deciding on the next steps to take on this issue.

A.05 A.O.B.

No issues raised under this agenda item.


Octyl gallate (E 311) and dodecyl gallate (E 312) are substances authorised as antioxidants in a variety of foods, as well as in food flavourings, in accordance with Annexes II and III to Regulation (EC) No 1333/2008.

The safety of octyl gallate (E 311) and dodecyl gallate (E 312) was recently re-evaluated by EFSA in the context of the programme for the re-evaluation of approved food additives required by Regulation No 1333/2008. EFSA was not able to confirm the safety of octyl gallate and dodecyl gallate as food additives due to a lack of toxicological data and therefore concluded that the present group Acceptable Daily Intake (ADI) for propyl gallate (E 310), octyl gallate (E 311) and dodecyl gallate (E 312) should no longer be valid.

On 30 May 2017 the Commission launched a public call for scientific and technological data on propyl gallate (E 310), octyl gallate (E 311) and dodecyl gallate (E 312), targeting the data needs identified in EFSA’s Scientific Opinion on the re-evaluation of those substances as food additives (http://ec.europa.eu/food/safety/food_improvement_agents/additives/re-evaluation_en). However, no business operator committed to providing the requested data for octyl gallate (E 311) and dodecyl gallate (E 312). Without those data EFSA cannot complete the re-evaluation of the safety of octyl gallate and dodecyl gallate as food additives and consequently it cannot be determined whether those substances still fulfil the conditions pursuant to Article 6(1) of Regulation (EC) No 1333/2008 for inclusion in the Union list of approved food additives. It is therefore appropriate to remove octyl gallate (E 311) and dodecyl gallate (E 312) from the Union list of approved food additives.

The draft Regulation presented by the Commission to the Committee concerned therefore the amendment of Annexes II and III to Regulation (EC) No 1333/2008 and the Annex to Regulation (EU) No 231/2012 by deleting octyl gallate (E 311) and
dodecyl gallate (E 312) from the Union list of authorised food additives. This Regulation should enter into force on the twentieth day following that of its publication in the Official Journal of the European Union. Foods containing octyl gallate (E 311) and/or dodecyl gallate (E 312) that would have been lawfully placed on the market before the entry into force of this Regulation would continue to be marketed until 6 months after the entry into force of this Regulation. In connection with this proposed transitional period, some Member States asked the Commission to have a general discussion on the appropriate use of transitional periods in measures concerning food additives.

**Vote taken:** Favourable opinion.


Cochineal, Carminic acid, Carmines (E 120) is a substance authorised as a colour in a variety of foods in accordance with Annex II to Regulation (EC) No 1333/2008. The safety of Cochineal, Carminic acid, Carmines (E 120) was recently re-evaluated by EFSA in the context of the programme for the re-evaluation of approved food additives required by Regulation (EC) No 1333/2008. EFSA concluded that the present dataset did not give reasons to revise the Acceptable Daily Intake (ADI) value for E 120 and that the refined exposure estimates were below the ADI for all population groups. However, the Authority recommended to revise the current title ‘Cochineal, Carminic acid, Carmines’, so that it would more accurately reflect the material used as a food additive and to update the specifications as regards the percentage of material not accounted for, the maximum limits for toxic elements and the presence of proteinaceous compounds.

The draft Regulation presented by the Commission to the Committee concerned therefore the amendment of Annex II to Regulation (EC) No 1333/2008 and the Annex to Regulation (EU) No 231/2012 as a follow-up to the recommendations made by EFSA. This draft Regulation should apply 12 months after its entry into force.

**Vote taken:** Favourable opinion.


The Commission received an application for the amendment of specifications concerning the food additives E 491 Sorbitan monostearate, E 492 Sorbitan tristearate and E 495 Sorbitan monopalmitate, i.e. the removal of the congealing range from the Union specifications.

The European Food Safety Authority evaluated the safety of an amendment of the specifications for those food additives as requested, and concluded that it would not
be of a safety concern. However, EFSA noted that this removal would result in less characterisation of the various sorbitan esters, and that this identification parameter could be replaced by another one.

Consequently, it is appropriate to amend the Union specifications regarding the removal of the ‘congealing range’ as an identification parameter for those three food additives and to replace it by 'Identification test - by acid value, iodine value, gas chromatography'.

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 and safety evaluation performed by EFSA.

Vote taken: Favourable opinion.


The Commission received an application for the authorisation of the use of low-substituted hydroxypropyl cellulose (L-HPC) as a food additive in food supplements in tablet form.

The European Food Safety Authority evaluated the safety of L-HPC as a food additive and concluded that there was no safety concern for the proposed use in food supplements in solid form (tablet), at a maximum use level of 20,000 mg/kg and a typical use level of 10,000 mg/kg.

Therefore, it is appropriate to include low-substituted hydroxypropyl cellulose (L-HPC) in the Union list of food additives and to assign E 463a as E-number to that additive to enable its authorisation in food supplements in solid form (tablet).

The draft Regulation presented by the Commission to the Committee concerned therefore the amendment of Annex II to Regulation (EC) No 1333/2008 and the Annex to Regulation (EU) No 231/2012 as a follow-up to an application and safety evaluation performed by EFSA.

Vote taken: Favourable opinion.


No discussion, no vote took place because the working document was not available.

Vote Postponed

Following discussions with Member States at the Working Party of Governmental Experts on Additives about some difficulties with the implementation of food category 17 ‘Food Supplements’ within Annex II to Regulation (EC) No 1333/2008, the Commission took the initiative of reorganising that food category.

Therefore, food subcategory 17.3 was deleted and food additives' entries that were included therein were transferred to either subcategory 17.1 or 17.2 to ensure transparency and legal certainty regarding the use of food additives in those foods.

To clarify whether a maximum (use) level for the food additives in food category 17 applies to the food as marketed or to the food ready for consumption, an introduction section referring to certain food additives authorised in that food category was included.

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 discussions with the EU Member States.

Vote taken: Favourable opinion.


The draft was presented and discussed. The measure authorises for a limited duration of 5 years the flavouring pyroligneous distillate for use in the traditional spirits *tuzemak* and *tuzemský* from the Czech Republic and the Slovak Republic only. The measure includes a number of restrictions concerning the use this flavouring in these specific spirit drinks. It will be applicable from 23 April 2018 as the transition period laid down in 'Regulation (EU) No 873/2012 ends on 22 April 2018.

Vote taken: Favourable opinion.

B.08  Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Regulation (EU) No 873/2012 of 1 October 2012 on transitional measures concerning the Union list of flavourings and source materials set out in Annex I to Regulation (EC) No 873/2012 as regards the extension of the transition period of Article 4 concerning the flavouring 'grill flavour concentrate (vegetable)' FL no. 21.002.

This measure concerns the extension of the transition period for the flavouring 'grill flavour concentrate (vegetable)' FL no. 21.002 which is the object of an application under the transition period of Regulation (EU) No 873/2012. For this product EFSA has requested additional information to be provided by August 2018 and therefore the EFSA assessment could not be made available before the end of the transition period (22 April 2018).
The measure contains a provision to ensure that it will be applicable from 23 April 2018 as the transition period laid down in Regulation (EU) No 873/2012 ends on 22 April 2018.

A number of member states considered that the application on two other flavourings FGE 502 Grillin’5078 and FGE 503 Grillin’CB-200 SF should receive the same consideration and asked for an equal treatment of all the 3 grilling flavouring products that applied for an authorisation, not only 'grill flavour concentrate (vegetable)' FL no. 21.002.

EFSA has delivered opinions on these two other applications FGE 502 Grillin’5078 and FGE 503 Grillin’CB-200 SF, and has not been able to conclude on the safety of these products on the basis of the information provided by the applicant.

As part of the discussions, the UK provided the following statement:

"The UK is gravely disappointed that the proposed measure does not provide for the temporary extension of the transitional period established in Article 4 of Regulation (EU) No 873/2012 for all three grill flavourings including FGE 502 Grillin’5078 and FGE 503 Grillin’CB-200 SF which we consider to be within the evaluation process.

Both FGE 502 Grillin’5078 and FGE 503 Grillin’CB-200 SF are the subject of equivocal EFSA opinions resulting from a lack of data and in our view, do not as such provide sufficient legal certainty. Their exclusion from this proposal will result in the removal these products from the market despite no proven safety concerns. This is an undesirable precedent as further scientific studies are being undertaken by the applicant which would enable for a more thorough assessment of their safety to be made.

In accordance with the objectives of Regulation (EC) No 1334/2008 it would have been more appropriate to extend the transitional period for all three grill flavouring applications until such time that a more robust assessment of their safety can be carried out and subsequent risk management measures become justifiable. This approach enjoyed significant support from Member States and would have ensured a consistent treatment of the three grill flavouring applications."

**Vote taken:** Favourable opinion.

**B.09 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) correcting Commission Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods.**

The Commission presented the draft and the Committee delivered its opinion with no objections (Advisory procedure). A Member State expressed its concerns about the inclusion of the category “food supplements” in the entry phytosterols/phytostanols in the proposal. The Commission provided the legal arguments which justify this inclusion.

**Vote taken:** Favourable opinion.

The Commission presented the draft Commission Implementing Regulation (EU) authorising the placing on the market of hen egg white lysozyme hydrolysate as a novel food and the Committee delivered its opinion with no objections.

**Vote taken:** Favourable opinion.


The Commission presented the draft Commission Implementing Regulation (EU) authorising an extension of use of UV-treated baker’s yeast (Saccharomyces cerevisiae) as a novel food and the Committee delivered its opinion with no objections.

**Vote taken:** Favourable opinion.


The Commission presented the draft Commission Implementing Regulation (EU) authorising an extension of use of UV-treated mushrooms as a novel food and the Committee delivered its opinion with no objections. A Member State abstained since it was in favour of maintaining an upper limit of 10 μg/100 g fresh weight for vitamin D in UV-treated mushrooms.

**Vote taken:** Favourable opinion.


The Commission presented the draft Implementing Regulation authorising the extension of use of oil from the micro algae *Schizochytrium sp.* as a novel food to a new food category in addition to the uses already authorised.

**Vote taken:** Favourable opinion.