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

CIRCABC Link: https://circabc.europa.eu/w/browse/6b693e53-a6ac-42e5-8922-b75d2661b3cb

A.01 Approval of the 2018 Member States’ plans for monitoring of residues in accordance with Directive 96/23/EC.

The evaluation of the 2018 Member States’ plans by the Commission and by the European Reference laboratories was presented.

A Member State communicated in advance of the meeting its disagreement on the evaluation of its plan. It indicated that it had erroneously not included certain substances in the plan, while they are being analysed in practice. An update of the evaluation was requested. The Commission indicated that the Member States’ comments on the evaluation and the replies to them were uploaded on Circa BC. It is not the intention to prepare an update of the document with the summary evaluations of the European Reference Laboratories (EURLs). The Commission considers that the uploaded documents provide all the necessary information. However, as requested by the concerned Member State, a new version of the summary evaluations of the EURLs will be uploaded on Circa, in which one sentence on the general conclusion will be amended.

The approval of the residue monitoring plans of all Member States was agreed by the Committee.

Each Member State has ten further working days to provide comments on the plans. If no comments are received, the plans shall be deemed to be approved. This approval is done electronically in the residues application.

A.02 Action levels for DEET and icaridin in various commodities (for agreement by the Committee).

The Commission presented the contents of the discussion paper on action levels for DEET and icaridin in various commodities and discussed the comments, which were received on this paper.

Some Member States expressed their preference for setting maximum levels under Reg. (EC) No 1881/2006. However, because these residues don’t cause a risk to consumers, the majority of Member States was not in favour of discussing legal levels and many Member States supported the approach proposed by the Commission. Because there is no risk for consumers, it was agreed to rephrase ‘action levels’ to ‘reference values for intra EU trade’.
A Member State enquired towards the definition of ‘reference value for intra EU trade. It was explained that, when concentrations of the residues are present below these levels, the food business operator can be sure of the compliance of the product. When the concentrations of the residues exceed the reference values, it is up to the competent authority to decide on possible follow-up actions.

A Member State indicated that more information would be needed on the origin of residues in honey before reference values can be established. Therefore it was decided for the time being not to agree on such values for honey and to first gather more information on the source of such contamination.

The Committee agreed on the following reference values for intra EU trade:

**DEET-CAS134-62-3(N, N-Diethyl-meta-toluamide)**
- Pine nut kernels 0.5 mg/kg
- Berries and small fruits except grapes 0.1 mg/kg
- Wild fungi 1.0 mg/kg
- Herbal infusions from flowers and leaves 0.3 mg/kg
- Spices 0.5 mg/kg

**Icaridin-CAS119515-38-71(1-(1-methylpropoxycarbonyl)-2-(2-hydroxyethyl)piperidine)**
- Wild fungi 0.05 mg/kg
- Herbal infusions from flowers and leaves 0.5 mg/kg.

**A.03 Commission Implementing Regulation on reference points for action for non-allowed pharmacologically active substances present in food of animal origin - SANTE/10413/2015.**

The Commission presented the draft and explained its contents. The Member States were asked to state their position on the draft.

Several Member States expressed their support to the draft, lowering the current Reference Points for Action (RPAs), because it would facilitate the enforcement regarding misuses of these substances by third countries on products exported to the EU. Even though certain residues could originate from natural occurrence, it was considered unlikely that they would exceed the new RPAs. Some Member States indicated that a short transitional period of 2 years or less would be acceptable, while others would prefer a transitional period of 3 years.

Some Member States took a position against the lowering of RPAs, due to the cost of re-validating methods or because of the fear of no longer being able to use qualitative screening methods. The Commission reassured that methods to achieve the lower RPAs are available and already implemented by several labs. The EURIs confirmed to the Commission that screening methods can still be used and that they will assist the labs in extending the validated range of their methods to the lower concentrations.

Some Member States indicated that the cost of re-validating methods needs to be weighted out to the health benefits related to lowering the RPAs. Also the natural occurrence of certain residues was used as an argument against lowering the RPAs.
A large group of Member States was not able to take a position yet and committed to do so in writing by 2 October 2018.

A.04 Follow-up to the DG SANTE audit in India (from 16 to 27 April 2018) on the evaluation of the control of residues and contaminants in live animals and animal products including controls on veterinary medicinal products.

A Commission audit to India in April 2018 identified several deficiencies as regards the control of residues and contaminants in animals and animal products. The findings were discussed with the Member States who were advised to consider expanding their scope of testing of Indian aquaculture products, in particular for residues of antimicrobial substances. In addition to the already ongoing testing for chloramphenicol, tetracycline, oxytetracycline, chlorotetracycline and metabolites of nitrofurans, focus should also be put on the testing of macrolides, aminoglycosides, beta-lactams including cephalosporins, lincosamides, diaminopyrimidines and doxycycline.

A.05 Update on the review of the maximum levels for mercury in fish.

After internal discussion within the Commission, it has been decided to discontinue for the time being the review of the maximum levels (MLs) for mercury in fish. However the Commission would like to stress the importance of consumption advice related to mercury in fish and encourages Member States to:

- develop specific national consumption advice related to fish consumption, in order to fully achieve the beneficial effects of fish consumption, whilst limiting the risks of mercury toxicity. When developing this consumption advice, Member States shall especially include the frequency of fish consumption and the fish species consumed;

- communicate the specific national consumption advice to the consumers as well as to relevant health care workers, working with the consumer groups most at risk;

Member State welcomed that the maximum levels for mercury in shark and swordfish will remain at the existing level and indicated that also food business operators should be involved in the information activities on consumption advice.

A Member State enquired whether still an update of the exposure assessment will be requested to EFSA. At this stage this is not planned. However if Member States have new occurrence data available, they can always submit them to EFSA. Possible data on the effectiveness of consumption advice can be sent to the Commission.

A.06 Clarification as regards authorised forms of lactic acid (E 270).

Lactic acid (E 270) is included in the Union lists of authorised food additives in Annex II and III to Regulation (EC) No 1333/2008. Specifications are laid down in Regulation (EU) No 231/2012. A question was raised as regards what forms of the optical isomers are covered by the applicable specifications.

The Committee concluded unanimously the following:

EINECS (200-018-0) included in the specifications for E 270 laid down in Regulation (EU) No 231/2012 does not refer to any particular optical isomer but just to lactic acid (unspecified). The understanding of the Committee is that this reference covers optical isomers L-(+)-lactic acid, D-(-)-lactic acid as well as DL lactic acid.
The Committee noted that the provisions laid down in Part E of Annex II to Regulation (EC) No 1333/2008 restrict for certain foods (e.g. infant formulae) the use to L- (+)- form only. For other foods, for which no such restriction is indicated, all forms (i.e. L- (+), D- (-) and DL) may be used.

A.07 Use of polyols and acesulfame K (E 950) in chewing gum.

Annex II to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in food and their conditions of use. A question was raised on the understanding of Annex II as regards the use of acesulfame K in chewing gum with added polyols.

The Committee concluded unanimously the following:

In Part E of Annex II to Regulation (EC) No 1333/2008 in food category 05.3 ‘Chewing gum’ polyols are approved for use at quantum satis with the restriction ‘only with no added sugar’. Thus polyols can be used in chewing gums ‘with no added sugars’ as defined in Article 3(2)(e) of Regulation (EC) No 1333/2008. It applies to products ‘with no added sugars’ in which acesulfame K (E 950) is used as a flavour enhancer (i.e. the maximum use level 800 mg/kg applies) as well as to products in which acesulfame K is used as a sweetener (i.e. the maximum use level 2000 mg/kg applies).

The same principle applies to other substances authorised as both sweeteners and flavour enhancers in chewing as well (i.e. aspartame, thaumatin, neohesperidine DC, neotame and advantame).

A.08 Use of excessive amounts of antioxidants.

‘Antioxidants’ is a functional class of food additives defined in Annex I to Regulation (EC) No 1333/2008 as substances which prolong the shelf-life of foods by protecting them against deterioration caused by oxidation, such as fat rancidity and colour changes. They differ from another functional class ‘preservatives’, i.e. substances acting against microorganisms.

Certain food additives typically used as antioxidants (e.g. ascorbic acid-ascorbates, citric acid-citrates) are authorised in different food categories at quantum satis, i.e. to be used in accordance with good manufacturing practice, at a level not higher than is necessary to achieve the intended purpose and provided the consumer is not misled.

Currently, several cases of the use of high levels of antioxidants (especially in meat and fish) have been noticed for which their compliance with the quantum satis principle was put in question.

In this regard, the Committee unanimously concluded the following:

- Food additives authorised at quantum satis acting as antioxidants shall be used at a level not higher than is necessary to achieve the intended purpose, i.e. an antioxidant effect.

- The use of higher levels, e.g. to mask or replace the use of preservatives to avoid regulatory restrictions for preservatives and to extend the shelf-life and fresh appearance as if preservatives were used, is not in compliance with the quantum satis principle and thus not authorised.
- For the use of ascorbic acid-ascorlates (E 300-302) in tuna loins the level of no more than 300 mg/kg is regarded as sufficient to achieve the desired antioxidant effect[1].

[1] The Standing Committee takes into account the reported use levels for fish food categories captured in the EFSA opinion on the re-evaluation of ascorbic acid (E 300), sodium ascorbate (E 301) and calcium ascorbate (E 302) as food additives (EFSA Journal 2015;13(5):4087; http://www.efsa.europa.eu/en/efsajournal/pub/4087). The Standing Committee considers that at the current level of knowledge the highest maximum level reported in the EFSA opinion (300 mg/kg) represents the highest level justified as necessary to accomplish the desired antioxidant effect.

### A.09 Use of vegetable extracts rich in constituents performing a technological function.

Before the discussion was opened the Commission clarified that this agenda item relates to ‘plant extracts’ thus covering not only ‘vegetable extracts’ but also other extracts of plant origin.

The Standing Committee issued statements on “spinach extract containing high levels of nitrate used in sausages” in 2006[1] and on “the use of fermented vegetable broth, enriched with nitrite” in 2010[2].

Based on the Member States’ request, the use of plant extracts[3] rich in constituents capable of performing a technological function or rich in their precursors (converted to active constituents before or after addition to the food, e.g. by microorganisms) was discussed at the meeting of the Working party of Governmental Experts on Additives on 21-22 June 2018. The Commission has been made aware by Member States of industry practices which consist in adding plant extracts to food primarily for food additive functions while being erroneously claimed not to be used as food additives.

Consequently, the Committee reached unanimously the following outcome:

1. The validity of the statements of 2006 and 2010 was reconfirmed.

2. The scope of both statements shall not be limited only to (fermented/non-fermented) extracts containing high levels of nitrate/nitrite but it shall be generally applicable to all plant extracts which, when added to foods, achieve a level of constituents (or their precursors) capable of performing a technological function in foods.

3. Such use of extracts that deliver a technological function (e.g. preservative, antioxidant, stabiliser (colour stabiliser) etc.) in foods to which they are added is deemed a deliberate use as a food additive.

4. Consequently, such use is deemed to meet the definition of a food additive and so it shall comply with the conditions set out in the food additive legislation (including relevant specifications) and be labelled in accordance with the appropriate provisions for labelling of food additives.

5. A number of plant extracts can perform both flavouring and additive functions. When flavourings have a technological function as food additives, the food additive legislation shall apply. In this case the extracts cannot be claimed to be used as flavourings.

The Committee welcomed the draft opinion on the implementation of Commission Regulation (EU) No 2018/213 and the clarifications that the note brings. The document was endorsed unanimously by the Committee and the Commission informed the Committee that the opinion will be published on the Commission's website as soon as possible.

A.11 Status of paper napkins as food contact materials.

The Commission explained that although a document had been prepared to explain the understanding of the status of paper napkins as food contact materials (FCMs), as no common approach was found among Member States' experts of the FCM Working Group, it was considered by the majority of the experts that the note was not sufficiently useful. A Member State regretted that an agreement could not be found. The Commission stated that the issue was one of a number of similar issues concerning materials and articles which may be considered to be "reasonably expected to be brought into contact with food" (Article 1(2)(c) of Regulation (EC) No 1935/2004). The Commission stated that the issue could be discussed again in the FCM Working Group but moreover, would be considered as part of the ongoing evaluation of EU FCM legislation.

A.12 Feedback on the discussions held in recent meetings of the different Working Groups on contaminants in food on different topics.

The Committee was informed of the outcome of the discussions of the recent meetings of the Working group on contaminants:

- Erucic acid

  Following the targeted stakeholder consultation, the review of the maximum levels for erucic acid in food has been finalised at technical level and a draft Regulation shall be presented for opinion at a next meeting of the Committee.

- 3-MCPD esters and glycidyl esters

[3] Also referred to as vegetable/spice/fruit extracts/concentrates/mixtures or incorrectly referred to as flavourings.
stakeholder organisations (professional and consumer) on these possible maximum levels is foreseen.

- **Perchlorate**

  Possible maximum levels for perchlorate in fruits and vegetables, tea, herbal and fruit infusions, infant formula, follow-on formula, processed cereal based food for infants and young children and babyfood were presented. A targeted stakeholder consultation, involving the relevant stakeholder organisations (professional and consumer) on these possible maximum levels is foreseen.

- **Foreseen amendments to Commission Implementing Regulation (EU) 884/2014** of 13 August 2014 imposing special conditions governing the import of certain feed and food from certain third countries due to contamination risk by aflatoxins.

  The foreseen amendments relate to:
  
  - modification of competent authorities entitled to sign the health certificates (India, Ethiopia, Argentina, Brazil and Azerbaijan)
  
  - modification of Article 1(3) as regards the exemption of 20 kg lots
  
  - changes of control frequencies (for dried figs from Turkey)
  
  - transfer of certain entries currently in Regulation (EC) No 669/2009 (groundnuts from Bolivia, Gambia, Madagascar, Senegal and Sudan and watermelon seeds from Sierra Leone)
  
  - update of CN codes.

  The internal Commission consultation process is ongoing and it is foreseen to submit the draft Regulation to the Committee for opinion at the next meeting of the Committee.

- **Issues related to the application of Commission Implementing Regulation (EU) 884/2014**

  - Commodities in transit for which an own control has shown a non-compliance despite the presence of a health certificate, certifying compliance with EU legislation

    The Committee was informed of the situation that an own control by a potential buyer of a lot already on EU territory (in transit) has demonstrated that the concerned lot was not compliant with EU legislation as regards aflatoxins. The question was put forward as regards the obligation of the food business operator to inform thereof the competent authority and the recipient of the lot.

    Based on an analysis of the relevant provisions in Regulation (EC) No 178/2002, the Commission representative concluded that, according to these provisions, the operators are obliged to notify to the competent authority and to the recipient of the lot any finding of non-compliance, in particular when these lots are traded further and if there is the possibility that these lots will, at a later stage, be placed on the EU market. On request of certain delegations, the Commission indicated that a formal legal opinion will be requested on this question.
- Common Entry Document (CED) with electronic signature and stamp

Regulation (EU) 884/2014 provides that “The customs authorities shall authorise the transfer of the consignment to a DPI after favourable completion of the checks referred to in paragraph 2 and the relevant entries of part II of the CED (II.3, II.5, II.8 and II.9) are completed and subject to the physical or electronic presentation of a completed CED by the feed and food business operator or their representative to the customs authorities“.

However in the digital CED, no stamps and signatures are provided in box II.8 and II.9, but reference is made to national legislation providing that the physical stamp and signature are replaced by a “digital stamp and signature”.

The digital CED (i.e. without physical signature and stamp) is acceptable on the condition that:

- the national legislation of the country where the DPE is located provides for the possibility to replace the physical stamp and signature by a “digital stamp and signature”. Member States are requested to inform the Commission of such national legislation (such national legislation exists in Italy)

- such CEDs are transmitted from the competent authority of the DPE to the competent authority of the DPI in order to ensure that the documentary controls have effectively been performed by the competent authority at the DPE and been found satisfactory

- Lot of groundnuts initially destined for human consumption found not be compliant with EU legislation as regards aflatoxins and finally used for animal consumption as the levels found are compliant with the maximum levels of aflatoxins in feed – Completion of the CED.

It was clarified that in such cases the section I.16 of the CED, "not acceptable" has to be filled, the box "Use for another purpose" be ticked and Part III of the CED completed.

In addition, it is appropriate to mention under II.17 (the box - chemical contamination has to be ticked) that the lot is acceptable for use in "animal feed". If not possible under II.17, it is important that the information is available.

The competent authority of the country of destination does not need to sample and analyse the lot again but must ensure / verify that the lot is effectively used for animal feed and is not redirected for human consumption.

- Ochratoxin A (OTA)

Following the targeted stakeholder consultation and subsequent discussion in the Working Group, EFSA has been requested to provide an updated exposure assessment taking into account recent occurrence data and the comprehensive food consumption database. In addition, given that there are indications that there are new toxicity data available since the last EFSA opinion on OTA in
2006, the request includes also an update, if needed, of the hazard identification and characterisation.

Awaiting the outcome of this assessment, the discussions as regards possible maximum levels of ochratoxin A in food not yet covered by EU legislation are for the time being suspended.

- **Pyrrolizidine alkaloids**
  Maximum levels are discussed for tea and herbal infusions, herbal food supplements, (dried) culinary herbs and certain spices.

- **Ergot alkaloids**
  The technical discussions are ongoing related to a possible lowering of the maximum level for ergot sclerotia in unprocessed cereals, with the exception of corn and rice.

  Maximum levels for ergot alkaloids are discussed for rye milling products, barley, wheat, spelt and oats milling products and processed cereal based food for infants and young children.

- **Tropane alkaloids**
  The maximum level for atropine and scopolamine in processed cereal –based foods for infants and young children, containing millet, sorghum, buckwheat or their derived products is foreseen to be extended to processed cereal foods and baby foods for infant and young children containing corn.

  Furthermore, a maximum level for grains of millet, sorghum, buckwheat, corn and their derived products (milling products) for popped cereals (cornflakes) and herbal infusions is under discussion. In addition, it is to be considered if the maximum level cannot be set as a sum of atropine and scopolamine in particular as regards herbal infusions.

- **Alternaria toxins**
  Discussions are ongoing on the appropriate regulatory measure. A possibility is to set a guidance level for alternariol (AOH) alternariol monomethyl ether (AME) and tenuazonic acid (TeA) in certain foods, combined with a monitoring recommendation (including also tentoxin).

  Foods considered for guidance levels: processed tomato products, paprika powder, sunflower seeds, cereal based foods for infants and young children. Also for tenuazonic acid, it might be appropriate to consider a guidance level for millet grains, dried figs and (certain) tree nuts.

- **Citrinine**
  Taking into account recent occurrence data, the current maximum level of citrinin in food supplements based on rice fermented with red yeast *Monascus purpureus* is foreseen to be lowered to 100 µg/kg.

- **Opium alkaloids**
  Following the outcome of the EFSA opinion, maximum levels in poppy seeds for morphine equivalents (morphine + 0.2 x codeine) and thebaine are considered.
• Acrylamide
Discussions have been started on the setting of maximum levels necessary to ensure a high level of human health protection, complementary to the existing measures on mitigation of acrylamide in food (Commission Regulation (EU) 2158/2017). As a first step maximum levels for acrylamide in processed cereal based foods for infants and young children and baby food shall be considered.

• Furan
EFSA has identified a health concern related to the presence of furan and methylfurans in food but it is acknowledged that there are no sufficient occurrence data on methylfurans in certain foods to perform a reliable exposure assessment. Therefore a Commission Recommendation is being prepared to generate these data in coffee, jarred baby foods (jarred in the large sense: in containers, pouches, ..), potato crisps, .. in view of possible future risk management measures aimed at protecting public health.

Furthermore consideration is to be given to the possible setting of regulatory levels for furan in jarred babyfood (jarred in the large sense).

• T-2 and HT-2 toxin and deoxynivalenol (DON)
The Committee was informed that discussions will be initiated to review the existing maximum levels for DON, taking into account the modified forms (3-acetyldeoxynivalenol, 15-acetyldeoxynivalenol and deoxynivalenol-3-glucoside) and to set maximum levels for T-2 and HT-2 toxin and this within a comprehensive mycotoxin strategy including prevention measures, approaches to deal with the large year to year variation, mitigation measures, agricultural practices,..

• PAH court case

The Court has rejected the request.

• Recast 1881/2006
On request of a delegation, the Commission confirmed that the work on the recast of Regulation (EC) No 1881/2006 has resumed.

A.13 A.O.B.
No issue was raised.

This measure had been discussed at the earlier meeting which asked to send the text back to the Working Group on flavourings to address a few remaining technical issues. The amended text was presented and discussed. The measure amends the purity criteria concerning this substance and also introduces restrictions in certain food categories, taking into account the EFSA opinion. During the discussions a minor amendment was introduced as regards the food category non-alcoholic drinks, which reflects former discussions in the Working Group.

A Member State abstained because it considers that the measure does not sufficiently address the potential persistence in the environment of the substance.

**Vote taken:** Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food.

The Commission presented the draft Commission Regulation (EU) amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food. The proposal contained corrections concerning the use categories of three already authorised substances, the authorisation of three new substances, the setting of a group migration limit for one substance, and a clarification concerning the use of food simulants in the migration testing of food contact materials from certain categories of foods. The Committee delivered its opinion with no objections.

**Vote taken:** Unanimity.


The Commission presented the draft Commission Implementing Regulation authorising the placing on the market of refined shrimp peptide concentrate as a novel food and the Committee delivered its opinion with no objection.

**Vote taken:** Unanimity.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation authorising the placing on the market of bovine milk basic whey protein isolate as a novel food ingredient under Regulation (EU) No 2015/2283 of the European Parliament and of the Council.

The Commission presented the draft Commission Implementing Regulation authorising the placing on the market of bovine milk basic whey protein isolate as a novel food and the Committee delivered its opinion with no objection.

**Vote taken:** Unanimity.

The Commission did not present the draft Commission Implementing Regulation authorising the placing on the market of Allanblackia seed oil at the Committee as additional information requested from the applicant was not provided on time for the meeting. The vote will thus take place at a next Committee meeting.

Vote Postponed


The Commission presented the draft Commission Implementing Regulation authorising the placing on the market of cranberry extract powder as a novel food and the Committee delivered its opinion with no objection.

Vote taken: Unanimity.


The Commission cancelled the presentation of the draft Commission Implementing Regulation refusing the placing on the market of D-ribose as a novel food, as the applicant has presented additional information that now needs to be evaluated by EFSA. Thus, the vote did not take place.

Vote Postponed


The Commission presented the draft Commission Implementing Regulation authorising the placing on the market of xylo-oligosaccharides as a novel food and the Committee delivered its opinion with no objection.

Vote taken: Unanimity.

The Commission presented the draft Commission Implementing Regulation authorising the placing on the market of egg membrane hydrolysate as a novel food and the Committee delivered its opinion with no objection.

**Vote taken:** Unanimity.

B.10 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation revoking the designation of the Institute Superiori di Sanità, Rome, Italy, as a European Reference Laboratory for the residues listed in Annex I, Group B(3)(c) to Directive 96/23/EC.

The Commission presented the draft and explained its contents.

**Vote taken:** Favourable opinion.