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Health and Food Safety Directorate General

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**SUMMARY REPORT OF THE  
STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED  
HELD IN BRUSSELS ON 11 JUNE 2018  
(Section Novel Food and Toxicological Safety of the Food Chain)**

*CIRCABC Link:* <https://circabc.europa.eu/w/browse/e99f1ad9-986b-4351-a74f-0079abde8c06>

**A.01 Information and discussion on the revocation of 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 - SANTE/10513/2018 Rev.0.**

Currently the Istituto Superiore di Sanità / Roma / Italy, is designated as a European Reference Laboratory (EURL) for elements in products of animal origin.

Until recently the activities of the EURL for elements in food of non-animal origin were fulfilled by the Joint Research Centre (JRC). As the JRC decided to cease these EURL activities, it was decided to allocate all EURL activities related to elements in food into one EURL. Therefore a call was launched for a new EURL for metals and nitrogenous compounds in plant and animal products, to which the ISS in Rome applied. In the beginning of 2018 the EURL for metals and nitrogenous compounds in food and feed was attributed to DTU Denmark. As the scope of the current EURL for chemical elements in food of animal origin is now covered by this new EURL, and in order to avoid overlaps, a proposal is presented for revoking the designation of the ISS Rome as a EURL. A possible vote on this measure could be scheduled at the PAFF Committee meeting of 17 September 2018.

The Commission thanked the ISS Rome for all the excellent work it performed in its function as EURL for elements and wished them all the best in their future activities.

A Member State expressed the concern that the proficiency tests currently organised by the ISS Rome would need to be maintained in the coming years. The Commission reassured that these tasks will be taken over by the DTU Denmark. Also concerns were raised as regards elements, which are not metals like iodine. The Commission clarified that for iodine currently no maximum levels are set in the EU.

**A.02 Postponement of the deadline for 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 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, foresees for the submission of monitoring data to EFSA by 28 February 2019. As the JRC sampling and reporting guideline on mineral oil hydrocarbons is only expected to be published in the coming weeks and as the guidance on analytical

methods is expected to be finalised after summer, the Member States agreed on the extension of the reporting deadline until 1 October 2019. The deadline is extended for the reporting of the data as well as for performing additional sampling and analyses in 2019. Several Member States indicated to be in favour of an extension of the deadline until 2020. The Commission proposed to collect the data by 1 October 2019 and to assess at that stage whether a further data collection is needed. A Member State raised the concern that the already collected data would not comply with the upcoming guidance and would therefore be rejected. The Commission reassured that also the already collected data will be taken into account.

**A.03 Endorsement by the Committee of the working document on rules applicable to national and coordinated official controls programmes and annual reports by Member States on veterinary medicinal products and prohibited or unauthorised pharmacologically active substances in live animals and animal products - SANTE/11987/2017 Rev.0(2).**

The Commission presented the document and explained its contents. A Member State suggested to include also the coccidiostats, resulting from carry over from feed, into the scope of the veterinary medicinal products (VMP) monitoring plans. The Commission proposed to discuss in the Working Group whether to include them in the VMP or in the contaminants plans.

Several Member States considered the data submission to EFSA in the SSD format to be complicated and raised issues on the reporting of results for pesticides. The Commission proposed to contact EFSA for specific data reporting problems and to raise the general issues in the EFSA networking group on Veterinary Medicinal Products Residues Data Collection. As regards the reporting of pesticides EFSA is working on a system to avoid double reporting from 2019 onwards.

In response to some Member States questions, the Commission explained that a possible Implementing Regulation on national control plans for contaminants would be discussed in the Working Group on Industrial and Environmental contaminants.

A Member State enquired whether the examples of sampling frequencies in the document would be binding. The Commission confirmed that this is not the case; the sampling frequencies will be further discussed in the Working Group on Residues of Veterinary Medicines.

The Committee endorsed the general approach for the development of an Implementing Regulation on national and coordinated official controls programmes and annual reports by Member States on veterinary medicinal products and prohibited or unauthorised pharmacologically active substances in live animals and animal products. On the basis of this working document the drafting Working Group will now start working out the detailed provisions of the Implementing Regulation.

**A.04 Information and discussion on reference points for action for non-allowed pharmacologically active substances present in food of animal origin - SANTE/10413/2015.**

The Commission presented the document and explained its contents. The Commission stressed the general principle of setting Reference Points for Action (RPAs) at the lowest level which can reliably be confirmed by the laboratories. It informed that the newly proposed RPAs are within the validated range of 25% of the national reference laboratories, which means they are also technically achievable for the other

laboratories, upon re-validation of their methods. In order to allow sufficient time for the laboratories, to re-validate their methods, a transitional period of 2 years has been included in the proposal. The Commission reassured that the newly proposed RPAs would still allow the use of screening methods and that training on this could be provided by the EURLs.

In response to written Member States comments, requesting proof of the public health risks related to SEM and chloramphenicol, the Commission listed the available data, which point to the carcinogenic properties of these substances. Furthermore the Commission summarised the articles, received from Member States, on the natural occurrence of chloramphenicol in feed and in animal products due to residues in feed. Some of these studies don't reflect real life conditions and use unrealistically high feed concentrations, up to 20-fold higher than the maximum natural occurrence in feed, thereby leading to residues in animal products above the new RPA. The Commission explained that it would be very unlikely that naturally occurring residues in feed would lead to exceedance of the newly proposed RPA.

A few Member States welcomed the proposal and stressed the importance of enforcement of residues from illegal treatments. Some Member States stressed that they support the general principles described in the Regulation but nevertheless raised concerns on the analytical feasibility of the new RPAs. They indicated that a sufficient transitional period would be needed, possibly longer than 2 years. Some Member States questioned the cost/ health benefit ratio of lowering the RPAs and indicated to be in favour of keeping the existing RPAs.

As it appears that there is no consensus yet on the proposal, the Commission asked the Member States to reflect on which updated RPAs and transitional periods would be acceptable to them and asked to send written comments by 22 June 2018.

#### **A.05 Discussion and endorsement of a draft Commission Recommendation on the monitoring of acrylamide in certain foodstuffs.**

The Commission Regulation (EU) 2017/2158 establishes mitigation measures and benchmark levels for the reduction of the presence of acrylamide in certain categories of foodstuffs.

There are insufficient data available on the presence of acrylamide in certain foods within and outside the scope of this Regulation. The draft Recommendation therefore recommends that competent authorities and food business operators monitor the presence of acrylamide in such food in view of possible further risk management measures, in addition to those already provided by Regulation 2158/2017, to ensure a high level of human health protection. A non-exhaustive list of food categories/foods to be monitored is provided.

With the adoption of Regulation (EU) 2017/2158 and this Recommendation, Commission Recommendations 2010/307/EU on the monitoring of acrylamide levels in food and 2013/647/EU on investigations into the levels of acrylamide in food will become obsolete and therefore, it is foreseen to repeal these Recommendations.

The Committee endorsed the Recommendation. The internal consultations within the Commission services are still ongoing and in case these would result in significant changes, the draft Recommendation shall be resubmitted for endorsement.

**A.06 Discussion and endorsement of the guidance on the implementation of Regulation (EU) 2017/2158 of 20 November 2017 establishing mitigation measures and benchmark levels for the reduction of the presence of acrylamide in food.**

The guidance on the implementation of 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.

Guidance is provided on :

- Food products within the scope of the Regulation;
- The categorisation of the food business operators;
- The application of mitigation measures and benchmark levels;
- Sampling and analysis and record keeping;
- Use of colour guides.

The guidance document has been subject to extensive stakeholder consultation and discussions within the working group environmental and industrial contaminants. Following the discussions at the meeting, some further changes were agreed.

It was stressed that the guidance document is an evolving document and further additions /updates might be needed based on the experiences gained with the application of Regulation (EU) 2017/2158.

The Committee endorsed the guidance document with the changes agreed at the Committee.

The Committee was informed that it is foreseen to publish the guidance document on the website of the Directorate General for Health and Food Safety and that it shall be translated in all Union languages.

**A.07 Feedback from the Working Group on Industrial and Environmental contaminants on the discussion as regards maximum levels of acrylamide in food and requirements for sampling and analysis, PAHs in traditionally smoked meat and meat products and fish and fish products, 3-MCPD esters, furan and perchlorate.**

The Committee was informed that the discussions on the setting of maximum levels for acrylamide in food for infants and young children are foreseen at the next meeting of the Working Group on Industrial and environmental contaminants.

As regards sampling and analysis, the Committee was informed :

- that no changes are foreseen to the provisions of Regulation (EC) 333/2007 for the homogenisation of the food supplements in capsules and that the European Union Reference Laboratory (EURL) for processing contaminants shall perform investigations and provide best practice for the homogenisation of capsules;
- on the envisaged performance criteria for the analysis of 3-MCPD esters, glycidyl esters and acrylamide;

- that the EURL for processing contaminants shall provide advice on appropriate performance criteria for the analysis of furan and methylfurans (2-methylfuran, 3-methylfuran and 2,5 – dimethylfuran).

The Committee was also informed :

- on the envisaged provisions on polycyclic aromatic hydrocarbons (PAHs) in traditionally smoked meat and meat products and fish and fish products and of the setting of a maximum level for PAHs in powders of food from plant origin for the preparation of beverages;
- on the ongoing discussions on the setting of maximum levels for 3-MCPD esters in food. While there seems to be a large agreement on the maximum level to be established in infant formula and follow-on formula, two different approaches are still under discussion on the maximum level for 3-MCPD esters in vegetable oils: one single strict maximum level for all vegetable oils and fats or a specific lower maximum level for named vegetable oils and a higher level for other vegetable oils. Also the setting of a maximum level for 3-MCPD esters and glycidyl esters in fish oils is under discussion;
- on a possible monitoring recommendation for the presence of furan, 2-methylfuran, 3-methylfuran and possibly 2,5 dimethylfuran in certain foods (coffee, jarred baby food (including in baby food in containers, tubes, pouches) potato based crisps, ....);
- on the discussions as regards the setting of maximum levels for perchlorate in certain foods.

Finally, the Committee was reminded of the importance for Member States competent authorities to designate National Reference Laboratory/ies (NRL(s)) reflecting the full scope of the activities of the EURLs in the area of contaminants : EURL for metals and nitrogenous compounds, EURL for processing contaminants, EURL for mycotoxins and plant toxins and EURL for halogenated persistent organic pollutants.

#### **A.08 Feedback from Working Group on Food Contact Materials on 2-3 May 2018.**

The Commission's services summarised recent discussions of the Working Group on Food Contact Materials (FCMs) relating to ceramic materials and articles, on recycling of plastic for FCMs and on a possible monitoring recommendation.

On ceramics the Member States' experts agreed in the Working Group on the need to significantly reduce limits for lead and cadmium migration from ceramic materials and articles under Directive 84/500/EEC. The Working Group acknowledged and discussed the impact on industry and in particular, traditional and artisanal businesses, which the Commission will aim to mitigate, whilst taking into account the burden to Member States' Competent Authorities. The Commission stated that to further increase safety and to minimise burden to micro-enterprises, it also intends to seek to introduce measures aimed throughout the supply chain and not just focus at testing provisions for final materials. The Commission is also considering rules on glass and enamelled materials and articles, as these materials are indirectly affected by rules on ceramics. Since mainstream glass is generally safe, rules will aim to minimise compliance burden. The main point under discussion is on options for crystal glass, for which >24% lead oxide is used in its production. Discussions of the Working

Group have not yet been fully conclusive and will continue in the forthcoming Working Group meetings.

On recycling of plastics, the Working Group had been informed on the relevance of Commission policy on the circular economy which targets achieving 100% recycling rates for plastic packaging by 2030. Decisions are being prepared on approximately 140 recycling processes to ensure recycled plastic is safe for food contact use; the target for voting on these Decisions is by the end of 2018. Obligatory monitoring is being strongly considered in order to facilitate enforcement and generate more useful data to confirm the safety of recycled plastic FCMs in practice. The Commission reported that discussions had also taken place in the Working Group on ways of recycling other than mechanical recycling (i.e. chemical depolymerisation and use behind a functional barrier) and there is further consideration of whether there is a need to regulate these types of recycling processes. Further discussion will take place in the next Working Group meeting, 5–6 July 2018.

Lastly, the Commission reported that discussions took place on Commission Regulation (EC) No 284/2011 on special import conditions for melamine and polyamide kitchenware from China and Hong Kong. Although results from Member States' reports indicate a much improved rate of compliance, other data (e.g. from RASFF) indicates continued problems on the market. In order to have a better understanding of the rates of compliance outside the scope of the current Regulation and to coordinate Member States' monitoring of FCMs, the Commission has presented its plans to introduce a voluntary monitoring program for Member States, to be published in a Recommendation and to be undertaken over the next year. The results of this will also help to prioritise a possible future, regular monitoring program, which could be implemented under the Regulation 2017/625 on official controls. The list of FCMs and substances to be included in the immediate future voluntary monitoring program is still subject to discussion within the Working Group.

#### **A.09 Any Other Business.**

- Information on the editorial amendments to the draft Commission Regulation amending Annex II to Regulation (EC) No 1333/ 2008 of the European Commission Parliament and of the Council as regards food category 17 and the use of food additives in food supplements which received a favourable opinion of the Committee on 17 April 2018

The Commission presented the editorial amendments to the draft Commission Regulation amending Annex II to Regulation (EC) No 1333/2008 of the European Commission Parliament and of the Council as regards food category 17 and the use of food additives in food supplements which received a favourable opinion of the Committee on 17 April 2018.

The editorial amendments provided further clarity to the draft as regards its purpose and eliminated inconsistencies that might have led to ambiguities.

- Follow-up of votes on flavourings of 17 April 2018

The following information was shared with the Committee.

The two draft measures voted at the previous meeting of the Standing Committee on 17 April 2018 : B7 "Draft Commission Regulation amending Annex I to Regulation (EC) No 1334/2008 as regards inclusion of pyroligneous distillate in the Union list of flavourings" (document SANTE/10349/2018) and B8 "Draft Commission Regulation

amending Regulation (EU) No 873/2012 on transitional measures concerning the Union list of flavourings and source materials as regards the extension of the transition period of Article 4 concerning the flavouring 'grill flavour concentrate (vegetable)' FL no. 21.002." (Document SANTE/10350/2018) are under the scrutiny period by the European Parliament and the Council at present. The end of the scrutiny period is 30/7/2018 and 8/8/2018 respectively.

Foods to which rum ether (pyroligneous distillate) were added before 22 April 2018 are allowed in the market until the sell by date and exhaustion of the current stocks. From 22 April 2018 this flavouring can only be used for the manufacture of *tuzemák* and *tuzemský*.

**B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation authorising the placing on the market of dried aerial parts of *Hoodia parviflora* 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 (EU) authorising the placing on the market of dried aerial parts of *Hoodia parviflora* as a novel food and the Committee delivered its opinion with no objection.

**Vote taken:** Favourable opinion.

**B.02 Exchange of views and possible opinion of the Committee on a draft Commission Regulation authorising the changing of the conditions of use of the novel food lactitol under Regulation (EU) No 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 changing of the conditions of use of the novel food lactitol and the Committee delivered its opinion with no objection.

**Vote taken:** Favourable opinion.

**B.03 Exchange of views and possible opinion of the Committee on a draft Commission Regulation authorising the placing on the market of 1-Methylnicotinamide chloride 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 (EU) authorising the placing on the market of 1-Methylnicotinamide chloride as a novel food and the Committee delivered its opinion with no objection.

**Vote taken:** Favourable opinion.

**B.04 Exchange of views and possible opinion of the Committee on a draft Commission Regulation authorising the placing on the market of Pyrroloquinoline Quinone Disodium Salt 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 (EU) authorising the placing on the market of Pyrroloquinoline Quinone Disodium Salt as a novel food and the Committee delivered its opinion with no objection.

**Vote taken:** Favourable opinion.

**B.05 Exchange of views and possible opinion of the Committee on a draft Commission Regulation authorising the changing of the designation and of the specific labelling requirements of the novel food synthetic zeaxanthin 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 (EU) authorising the changing of the designation and of the specific labelling requirements of the novel food synthetic zeaxanthin as a novel food and the Committee delivered its opinion with no objection.

**Vote taken:** Favourable opinion.

**B.06 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards caffeine and theobromine.**

The draft was presented and discussed. The measure maintains the existing restrictions of these two flavouring substances, following the EFSA opinion. These flavouring substances are no longer considered under evaluation.

**Vote taken:** Favourable opinion.

**B.07 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards the substance N-(2-methylcyclohexyl)-2,3,4,5,6-pentafluorobenzamide.**

The measure was presented and discussed, following the EFSA evaluation. As there were a number of detailed comments regarding some provisions, it was decided to send the draft back to the Working Group on flavourings in order to clarify the issues raised and submit an amended draft at a forthcoming meeting of the Committee.

**B.08 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards the removal from the Union list of certain flavouring substances.**

The measure was presented and discussed. It refers to the withdrawal from the Union list of the three flavouring substances with Fl nos 07.127, 11.008 and 13.175 for which the persons responsible for placing them on the market have withdrawn the application.



**Vote taken:** Favourable opinion.