EUROPEAN COMMISSION

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 19 JUNE 2017

(Section Novel Food and Toxicological Safety of the Food Chain)

CIRCABC Link: *https://circabc.europa.eu/w/browse/3df0759c-a73f-43cb-b4f1-9b2a5b628bc2*

A.01 Feedback on issues discussed in recent meeting(s) of the Expert Committee Industrial and Environmental contaminants and the Expert Committee Agricultural Contaminants (details to follow).

a) 3-MCPD fatty acid esters and glycidyl fatty acid esters in fish oil

Findings of high levels of 3-MCPD fatty acid esters and glycidyl fatty acid esters in fish oil have been reported to the European Commission. In the EFSA opinion on 3-MCPD esters and glyciyl esters, no reference was made to findings of high levels of 3-MCPD fatty acid esters and glycidyl fatty acid esters in fish oil.
In order to have a clear view on the extent of the problem, the monitoring of presence of 3-MCPD fatty acid esters and glycidyl fatty acid esters in food supplements containing fish oil (fish body oil or fish liver oil) or other fish oil containing foodstuffs is recommended.
The relevant European stakeholder organisations have been informed of these findings and on the ongoing discussions at EU level.
Once EFSA has finalised their re-opening of the 3-MCPD fatty acid esters opinion and appropriate risk management measures are discussed as follow up, the appropriateness of setting MLs for glycidyl fatty acid esters and 3-MCPD fatty acid esters in food supplements containing fish oil (fish body oil or fish liver oil) and other fish oil containing foodstuffs shall be considered.

b) Erucic acid

Taking into account the outcome of the EFSA opinion on erucic acid in food and feed and following discussions in the Expert Committee, the Committee agreed that following possible maximum levels, referring to the level of erucic acid calculated on the total level of fatty acids in food are sent to the relevant stakeholder organisations for a targeted stakeholder consultation: 20.0 g/kg in vegetable oils and fats [with the exception of mustard oil and borage oil] and 4.0 g/kg in infant formulae and follow-on formulae. A level of 300 g/kg erucic in mustard oil used in gastronomy as flavour is suggested.

Finally a level of 30 g/kg of erucic acid in mustard on a whole weight basis is suggested for consultation.

c) Ergot alkaloids

It was agreed to base the discussion on possible maximum levels for ergot alkaloids on the sum of the following 12 ergot alkaloids : ergometrine, ergosine, ergocornine, ergotamine, ergocristine, ergocryptine and their respective -inine forms.

d) Pyrrolizidine alkaloids

The sum of the following 17 pyrrolizidine alkaloids (in accordance with the CONTAM Panel recommendation) was put forward for agreement as basis for the discussion on possible maximum levels for pyrrolizidine alkaloids
intermedine/lycopsamine, £
intermedine-N-oxide/lycopsamine-N-oxide,
senecionine/senecivernine,
senecionine-N-oxide/senecivernine-N-oxide,
seneci(o)phylline,
seneciphylline-N-oxide,
retrorsine,
retrorsine-N-oxide,
echimidine,
echimidine-N-oxide,
lasiocarpine,
lasiocarpine-N-oxide,
senkirkine
One delegation indicated that it is appropriate to include also europine, europine-N-oxide, heliotrine and heliotrine-N-oxide given the very high levels of these pyrrolizidine alkaloids found in certain spices.

e) citrinin

The Committee agreed that the data contained in the EFSA report on the presence of citrinin in cereals and cereal based foods do not require an immediate follow-up as regards risk management as regards cereal based foods as the findings of citrinin in cereal based food do not raise a particular health concern.
However based on the data available in the EFSA report, the Committee agreed that a review of the current maximum level of 2000 µg/kg (*) in food supplements based on rice fermented with red yeast Monascus purpureus is necessary and appropriate. Taking into account the available data, a level of 500 µg/kg could be used as starting point for the review of the maximum level of citrinin in food supplements based on rice fermented with red yeast Monascus purpureus.

(*) Regulation (EC) 1881/2006 provides that the maximum level is to be reviewed before 1 January 2016 in the light of information on exposure to citrinin from other foodstuffs and updated information on the toxicity of citrinin in particular as regards carcinogenicity and genotoxicity.

f) Feedback from the 11th session of the Codex Committee on Contaminants in Food and Feed (CCCF)

At the 11th session of CCCF in April 2017 a maximum level of aflatoxin total for ready to eat peanuts was discussed. After discussion it was concluded to request comments on the suggested maximum levels of 10 µg/kg or 15 µg/kg.

In preparation of the meeting of the 11th session of CCC, the EU had agreed to a position whereby the EU objected to the proposed level of 15 µg/kg. With the two options for maximum level currently put forward, i.e. 10 µg/kg and 15 µg/kg, the EU would be in a position to accept 10 µg/kg but not 15 µg/kg and this in line with the agreed position for the 11th Session of the CCCF. However in order to be able to accept the 10 µg/kg aflatoxin total as the level is deviating from the EU maximum level of 4 µg/kg, the Committee agreed that it is necessary to request EFSA to assess if the possible increase of the current EU-maximum level for aflatoxin total of 4 µg/kg in peanuts ready-to-eat to 10 µg/kg would not result in an unacceptable increase of the risk for public health taking into account vulnerable groups of the population and the EU consumption patterns.
The Commission intends to submit a request to EFSA in view of having that assessment available in advance of the next meeting of the CCCF.

g) Information on other issues under discussion

- Maximum levels of ochratoxin A for foodstuffs currently not yet regulated at EU level.

- Following-up on a conclusion at the Committee meeting on 8 February 2017 ("*awaiting the carrying out of the compound specific toxicity data, it is appropriate to consider the need to set maximum levels for Alternaria toxins of most concern in foods in which they can occur at high levels in order to ensure a high level of human health protection, in particular for vulnerable groups of the population*" discussions are currently ongoing for which *Alternaria* toxins (alternariol, alternariol monomethyl ether, tenuazonic acid or tentoxin) and for which food commodities possible maximum levels should be considered.

- The re-assessment of the derogation applied by certain Member States as regards the maximum levels for polycyclic aromatic hydrocarbons (PAH) in traditionally smoked meat, meat products, fish and fishery products is ongoing based on the information provided by the Member States and is expected to be finalised in the autumn of 2017. The derogation continues to apply after 1/9/2017 until new provisions reflecting the outcome of the abovementioned re-assessment are adopted.

- An exchange of views has taken place on the maximum level of mercury in swordfish and certain shark species. The positions as regards the appropriate maximum level for mercury in swordfish and certain shark species remain largely unchanged.

- The Commission's representative indicated to expect to be able to finalise the recast of Regulation (EC) 1881/2006 in the autumn of this year.

- Following the discussions at the Expert Committee, the Commission is currently elaborating a monitoring recommendation on certain contaminants in seaweed for discussion at the next meeting of the expert Committee.

h) Clarification on an issue discussed at the Standing Committee on 25 November 2016 as regards opium alkaloids in poppy seeds

Reference is made to the report of the above mentioned Standing Committee.
Following a request, it was clarified that the agreed target level of 10 mg/kg applies to poppy seeds placed on the market for final consumer.
As regards the application of this target level in business to business transactions, the application thereof should be limited to transactions whereby the poppy seeds are provided to a food business operator who places the poppy seeds on the market for a final consumer without any further physical treatment to reduce the opium alkaloid content or who uses the poppy seeds as ingredient in finished foods without any further physical treatment.
No comments were made by the Committee as regards this clarification.

Furthermore the Committee was informed of the call of 15 May 2017 for occurrence data on the different opium alkaloids in poppy seeds in relation with the ongoing assessment by EFSA. Member States have 2 months (until 15 July 2017) to submit occurrence data on opium alkaloids. Occurrence data submitted after this date cannot be taken into account in the EFSA assessment in order to have a timely delivery of the opinion. The EFSA WG agreed that only data on the individual alkaloids will be used and no data on the total alkaloids. Oripavine will be added to the list of compounds for which data can be submitted.
Member states are invited to provide the available monitoring data not yet provided to the EFSA database to provide these data by 15 July 2017. In case the deadline cannot be met but available data can be submitted within a reasonable time after this deadline(i.e. maximum a few weeks thereafter), Member States are invited to inform thereof EFSA before 15 July 2017 on the following email address: data.collection@efsa.europa.eu.

A.02 Exchange of views on the follow-up of the EFSA Opinion on the flavouring group FGE.208 Rev. 2.

An initial exchange of views took place on the follow-up to this opinion by EFSA on this group of substances. The discussions will continue, taking into account the earlier discussions and decisions on them.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) amending Annexes II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of ferrous lactate (E 585) in the mushroom *Albatrellus ovinus* used as an ingredient in *leverpastej.*

Vote postponed

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) amending Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards calcium sorbate (E 203).

Vote postponed

B.03 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 removal from the Union list of the flavouring substance 4,5-epoxydec-2(trans)-enal.

The Commission's representative presented the text of the draft Regulation.
The European Food Safety Authority has concluded in its opinion published on 31st May 2017 that the flavouring substance 4,5-epoxydec-2(trans)-enal (Fl 16.071), under evaluation, raises a safety concern with respect to genotoxicity as there is a genotoxic effect observed in the liver of rats in the in vivo assay submitted.
Its use as flavouring substance therefore does not comply with the general conditions of use of flavourings set out in the relevant legislation.
The draft Regulation proposes to remove this flavouring substance from the Union list of flavourings and source materials and prohibit its use in and on food from the date of application of the draft Regulation using the urgency procedure foreseen in Article 7(6) of the Regulation (EC) 1331/2008.

The UK made following statement :

"*The UK cannot support this measure at this time. It is not clear from the EFSA opinion that the agreed consensus criteria for the evaluation of results in the OECD test guidelines have been followed. We consider that if the guideline had been followed the in vivo test may have ruled out a genotoxic concern and therefore urgent risk management action would not be justified. We consider that it is important for EFSA to provide additional clarification on this matter before any risk management action is considered. The UK also considers that the proposed legislation is not consistent with previous risk management measures to remove suspected genotoxic substances as the transitional periods have been removed*."

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision authorising the placing on the market of *L-ergothioneine* as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council.

The Commission's representative presented the draft Implementing Decision authorising the placing on the market of *L-ergothioneine* as a novel food ingredient.

Vote taken: Favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision authorising the placing on the market of an enzyme preparation of prolyl oligopeptidase produced with a genetically modified strain of *Aspergillus niger* as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council.

The Commission's representative presented the draft Commission Implementing Decision authorising the placing on the market of an enzyme preparation of prolyl oligopeptidase produced with a genetically modified strain of *Aspergillus niger* as a novel food ingredient.

Vote taken: Favourable opinion.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) No 2015/949 as regards withdrawal of groundnuts (peanuts) from the United States of America from the list of approved pre-export checks as regards aflatoxins.

Article 23 of Regulation (EC) No 882/2004 provides that specific pre-export checks that a third country carries out on feed and food immediately prior to export to the European Union with a view to verifying that the exported products satisfy Union requirements may be approved. Such an approval may only be granted to a third country if an European Union audit has shown that feed or food exported to the European Union meets Union requirements or equivalent requirements and that the controls carried out in the third country prior to dispatch are considered sufficiently effective and efficient as to replace or reduce the documentary, identity and physical checks laid down in EU law. Such an approval of pre-export checks performed by the United States of America (US) authorities on aflatoxins in groundnuts was granted by the EU in 2008 and was included in Commission Implementing Regulation (EU) No 2015/949, which groups together all approved pre-export checks carried out on certain food by certain third countries as regards the presence of certain mycotoxins.

An increase of non-compliance as regards the presence of aflatoxins in groundnuts from the US has been observed since mid-2016. The US authorities were informed thereof and commitments were made to remediate the situation. However it could be observed that the situation has not been improved. It is therefore concluded that the conditions leading to the approval of the pre-export controls are no longer fulfilled and therefore the proposed draft Regulation removes groundnuts (peanuts) from the US from the list of approved pre-export checks.

The Committee was informed of the information provided by the US authorities to the Commission prior to the meeting.

The Committee was furthermore informed that consideration of further going measures as regards the presence of aflatoxins in peanuts from US shall take place in the autumn. The following elements shall be taken into account in this consideration :

- the evolving of the situation in recent months as regards non-compliant findings at import of aflatoxins in peanuts from US;
- the outcome of the audit of the Directorate Health and Food audits and analysis of the DG Health and Food Safety of the European Commission, which is foreseen to take place in September 2017 as regards controls in place in the US on the presence of aflatoxins in pistachios and peanuts intended for export to the EU; and
- the commitments made by the US authorities to remediate the situation.

No comments were made as regards the draft Regulation.

Vote taken: Favourable opinion.

C.01 Exchange of views of the Committee on a draft Commission Implementing Regulation amending Implementing Regulation (EU) No 2016/6 of 5 January 2016 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 draft Implementing Regulation was presented. A discussion on the draft Implementing Regulation took place in view of launching the text for public consultation on the better regulation portal and a vote at a next meeting of the Committee.

Although no major comments on substance were raised, some delegation were of the opinion that it is appropriate to strictly apply the established criteria for delisting or relisting commodities for systematic testing by Japanese authorities before export to EU. Furthermore some Member States raised the reciprocity issue as regards the regionalisation.

C.02 Exchange of views of the Committee on a draft Commission Regulation (EU) amending Regulation (EU) 1881/2006 as regards maximum levels of glycidyl esters in vegetable oils and fats, infant formula and follow-on formula.

The draft Regulation was presented.

The Scientific Panel on Contaminants in the Food Chain (CONTAM) of the European Food Safety Authority (EFSA) adopted a scientific opinion on the risks for human health related to the presence of 3-and 2-monochloropropanediol (MCPD) and their fatty acid esters and glycidyl fatty acid esters in food.
EFSA has decided to re-open the 3-MCPD and their fatty acid esters assessment following a detailed analysis of the divergence in opinion between Joint FAO/WHO Expert Committee on Food Additives (JECFA) and EFSA on 3-MCPD and their fatty acid esters in view of the updated guidance of the EFSA Scientific Committee on the use of benchmark dose approach in risk assessment. Therefore it is was agreed to await the outcome of the re-opening of the 3-MCPD and their acid esters before taking appropriate regulatory measures.

Glycidyl fatty acid esters are food contaminants found at highest levels in refined vegetable oils. Glycidyl fatty acid esters are hydrolysed to free glycidol in the gastrointestinal tract.

The CONTAM Panel concluded that glycidol is a genotoxic and carcinogenic compound. In view of the genotoxic and carcinogenic potential of glycidol, a margin of exposure (MoE) approach was applied. Scenarios of exposure in infants receiving formula only resulted in a MoE of about 5500 to 2100. A MoE of 25,000 or higher was considered of low health concern.

The draft Regulation therefore provides for the establishment of a maximum level of glycidyl fatty acid esters in vegetable oils and fats placed on the market for the final consumer or for use as an ingredient in food, with a stricter maximum level for vegetable oils and fats intended for use in baby food and processed cereal-based food. Strict maximum levels are also proposed to be set in infant formula, follow-on formula and food for special medical purposes intended for infants and young children, taking into account what is currently achievable by applying good practices. However there is a need to further reduce the presence of glycidyl fatty acid esters in infant formula, follow-on formula and food for special medical purposes intended for infants and young children and therefore it is foreseen to establish stricter maximum levels applicable within a defined period of time, enabling food business operators to perform the necessary changes to the production to achieve this lower level and to ensure that a reliable method of analysis is available to effectively enforce these strict levels.

A discussion on the draft Implementing Regulation took place in view of launching the text for public consultation on the better regulation portal and a vote at a next meeting of the Committee.

No major comments were raised, although some delegations raised some reluctance as regards the stricter maximum levels in infant formula, follow-on formula and food for special medical purposes intended for infants and young children to be applicable within a defined period of time.

C.03 Exchange of views of the Committee on a draft Commission Regulation establishing mitigation measures and benchmark levels to reduce the presence of acrylamide in food.

The Committee was informed that the draft Regulation has been published on Friday 9 June 2017 on the better regulation portal for a 4-week public consultation.
The link to the consultation is :
http://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-2895100_en.

Discussion has taken place on certain aspects of the regulation such as the delineation between the different categories of food business operators which have to apply a different level of mitigation measures, the concept of benchmark levels.

The Commission indicated the possibility that the Commission shall organise an additional meeting of the Committee before the summer break after the expiry of the

4-week public consultation in view of submitting the draft Regulation for opinion to the Committee. This will depend of the comments received during the public consultation and from the competent authorities of the Member States. Therefore, the Member States were invited to send in their comments in advance to the Commission and to inform the Commission of comments made during the public consultation, which are supported by the competent authority.

C.04 Exchange of views of the Committee on a draft Commission Regulation (EU) amending Annex VII to Regulation (EC) 882/2004 of the European Parliament and of the Council as regards the EU reference laboratories in the field of contaminants in feed and food.

The Joint Research Centre (JRC) of the European Commission currently hosting the EU reference laboratory for heavy metals in feed and food, the EU reference laboratory for polycyclic aromatic hydrocarbons (PAHs) and the EU reference laboratory for mycotoxins in feed and food since 2006, has informed the Directorate General for Health and Food Safety no longer to continue to host these EURLs as from 1 January 2018.

In these areas the effectiveness of official controls and other control activities depend on the quality, uniformity and reliability of the methods of analysis and analytical results performed by the official laboratories and there is a continued need to promote uniform practices in the use of analytical methods. EU reference laboratories contribute to the improvement and harmonisation of use of analytical methods used by official laboratories. It remains important necessary to maintain an EU reference laboratory in these areas and therefore new EU reference laboratories should be designated for these areas. As since 2006, new priorities have been identified in the field of metals, nitrogenous compounds, processing contaminants and plant toxins, it is necessary to widen the scope of the new EU reference laboratories to be designated.

The scope of the current EU reference laboratory for heavy metals in feed and food is therefore extended to all metals and nitrogenous compounds in feed and food, of the current EU reference laboratory for Polycyclic Aromatic Hydrocarbons (PAH) to all processing contaminants and of the current EU reference laboratory for mycotoxins in feed and food to mycotoxins and plant toxins in feed and food.

The Commission launched on 23 January 2017 a call for applications to select and designate an EU reference laboratory for these areas. The call is closed and the evaluation of the received applications is ongoing.

Given the growing importance of chlorinated persistent contaminants other than PCBs and dioxins, brominated persistent contaminants and fluorinated persistent contaminants for the safety of feed and food, it is also necessary to extend the scope of the EU reference laboratory for dioxins and PCBs in feed and food to all halogenated persistent organic pollutants (POPs) in feed and food. Therefore the EU reference laboratory for dioxins and PCBs in feed and food is proposed to be renamed in EU reference laboratory for halogenated persistent organic pollutants (POPs) in feed and food to reflect this extension of scope.

No comments were raised by the Committee and the commission representative informed the Committee to submit the draft Regulation for at a next meeting of the Committee, once the evaluation of the received applications is finalised.

M.01 A.O.B.

A delegation requested to explain the factors and/or criteria leading to put confidentiality disclaimers on documents for working groups and for the standing committee and to explain what are the possible consequences of those disclaimers on consultation processes at national level. The concern was expressed that such disclaimer could hinder the national obligation of consultation and the work of member states experts to elaborate reasoned positions on issues.

The Commission representative answered that the objective of the disclaimer is to be very clear about the preparatory nature of the document and to ensure that the document is presented in such a way that it cannot be confused with an act or draft act endorsed or adopted by the College. The disclaimer is not meant to change the Commission practice to consult with Member States, neither is it meant to impact or restrict the possibility for Member States to carry out their preparatory work. Also in that work the disclaimer will help to be clear about the nature of the document. The disclaimer states that the document 'may contain confidential and/or privileged material'. If that was the case for a specific draft act general rules on classification of documents would in any case have to be followed.