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 17 NOVEMBER 2017

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

CIRCABC Link: *https://circabc.europa.eu/w/browse/9d098100-1837-4f93-ac66-2f4335086dcc*

A.01 Flavourings

A.01.1. Follow-up of EFSA opinion on rum ether

The follow-up to this EFSA opinion was discussed. Further technical discussions on a possible course of action will take place at the Working Group on flavourings scheduled on 20 December 2017.

A.01.2. Exchange of views on parts B, C, D, and F of Annex I of Regulation 1334/2008

The Committee endorsed the following statement :

By the end of the transition period laid down in Article 3 of Regulation (EU) No 873/2012 after the establishment of the Union List of Flavourings with Regulation (EU) No 872/2012 , which finished on 22 October 2015, there was no application submitted in accordance with the Regulation (EC) No 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings concerning the following categories of flavourings :

- Part B : Flavouring preparations;
- Part C : Thermal process flavourings;
- Part D : Flavouring precursors;
- Part F : Source materials.

Therefore, these parts of the Annex I of the Regulation remain empty.

As a consequence no product belonging to these categories of flavourings has been authorised and therefore no product belonging to these categories of flavourings are allowed to be on the EU market or be used in the European Union as of 22 April 2018.

Applications for authorisation under any of these categories of flavourings should be submitted under the Common Authorisation Procedure of Regulation (EC) No 1331/2008.
The flavouring substances belonging to the category 'substances' are include in Part A of Annex I of Regulation 1334/2008. There have been applications submitted during the transition period concerning Part E: 'other flavourings' and these applications are currently under evaluation.
As regards the category 'smoke flavourings' the Union list is established by Regulation (EU) No 1321/2013.

A.01.3. Exchange of views on a general approach to follow when a flavouring substance under evaluation (included in the Union list of flavourings and with a footnote in 2012) belongs to a group where the representative substance is evaluated as genotoxic by EFSA.

The approach to follow in case other similar cases arise in the future during the evaluation of flavouring substances in the evaluation program similar to the group represented by the substance p-mentha-1,8-dien-7-al (FL 05.117) was endorsed with a small modification.

A.02 Feedback from recent meetings of Expert committee on contaminants. (Details to follow)

The Commission representative informed the Committee of following issues:

- Envisaged topics on acrylamide for discussion in view of providing guidance to implement the envisaged Regulation establishing mitigation measures and benchmark levels for the reduction of the presence of acrylamide in food:

    a. Guidance on the categorisation of food business operators as regards the application of mitigation measures (Annex I, Annex IIA, or Annex IIA+B of the envisaged Regulation);
    b. Sampling /enforcement in view of application of the envisaged Regulation;
    c. Monitoring of presence of acrylamide in food commodities not covered by the envisaged Regulation;
    d. Initiation of the discussion on maximum levels for certain foods;
    e. On the variation of acrylamide levels within a certain broad category of foodstuffs in order to facilitate the implementation /enforcement when benchmark levels are exceeded;
    f. Awareness campaigns towards food business operators and consumers;
    g. Provisions on sampling and analysis (amendment to Regulation (EC) No 333/2007)
    h. Any other issue of relevance.

- Envisaged topics for discussion at next working group meetings of industrial and environmental contaminants:

a. Follow-up to EFSA opinion on furan and methylfurans;
b. Follow-up to updated EFSA exposure assessment to perchlorate;
c. Follow-up to expected updated opinion as regards 3-MCPD esters, 3-MCPD esters and glycidyl esters in fish oil and amendment to Regulation (EC) 333/2007 as regards analytical performance criteria of 3-MCPD esters and glycidyl esters;
d. PAH in traditionally smoked meat and meat products and traditionally smoked fish and fishery products.

- Envisaged topics for discussion at next working group meeting of agricultural contaminants (scheduled on 27 November 2017)

a. Pyrrolizidine alkaloids in honey, tea, herbal infusions and food supplements;
b. Ergot alkaloids;
c. Deoxynivalenol and modified forms;
d. T-2 and HT-2 toxin;
e. Alternaria toxins;
f. Erucic acid;
g. Citrinine;
h. Ochratoxin A.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision authorising the placing on the market of N-acetyl-D-Neuramic acid 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 N-acetyl-D-Neuramic acid as a novel food ingredient.

Two Member States voted against and one abstained citing disagreement with the use of warning labelling as they are of the opinion that food supplements should be generally safe and exposure concerns for infants, young children and children under the age of ten should not be addressed by a warning labelling.

Vote taken: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision authorising the placing on the market of oil from Calanus finmarchicus 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 oil from Calanus finmarchicus as a novel food ingredient.

One Member State abstained as they are of the opinion that children should be excluded for consumption of these food supplements containing oil from Calanus finmarchius.

Vote taken: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods.

The draft Commission Regulation has been published on 19 July 2017 on the better regulation portal for a 4-week public consultation (https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-3649060_en).
The period of public consultation ended on 16 August 2017.

In total, six comments were submitted, notably in the last days of the public consultation.

Of these six comments, four were received from business associations and two from individual companies.

More in detail, comments were received from :

- the following business associations: FDE (FoodDrinkEurope), IPIFF (International Platform of Insects for Food and Feed), FSE (Food Supplements Europe) and ELC (EU Specialty Food Ingredients)
- the following individual companies: Intertek and an anonymous company.

The comments relate mainly to the following issues (not exhaustive) :

- The need to refer to EFSA guidance
- The need to keep 2 January 2020 as the deadline for the transitional measures
- The need to include the post-market monitoring requirements in the proposal
- The need to include examples of non-valid dossiers
- The need to include further provisions for applying data protection
- The need to define verifiable justification.

The Commission's representative provided the following information :

The EFSA guidance on novel foods cannot be referred to in the draft Implementing Regulation as the Commission does not have a formal control on it.

Regarding the transitional measures, the new novel food regulation provided for a transitional period allowing food business operators to continue placing products on the market without such EU authorisation until their request for placing the product on the market has been decided upon. The Commission has been empowered in the novel food Regulation adopted on 25 November 2015 to set the deadline until such applications will be considered for no later than 2 January 2020. The Commission has

set the deadline of 1 January 2019 for novel food applications in the draft implementing Regulation. This deadline takes account of the legitimate rights of food business operators as it ensures that the food business operators gain legal certainty about the legality of their product in the market as quickly as possible. Food business operators were aware of the requirements of an authorisation being applicable to them as of 1 January 2018 already with the adoption of the novel food Regulation on 25 November 2015 and therefore could prepare for the changes introduced by the new regime. The deadline set in the implementing act grants them one more year to finalise their applications.

The need to include further provisions for applying data protection is not in the scope of the draft implementing Regulation.

The draft Implementing Regulation submitted for public consultation has been amended to take into account the comments made during that consultation period. The amended draft Implementing Regulation was submitted to the Committee for opinion.

A Member State made the following statement : *"the data provided in the application to enable the comprehensive risk assessment must encompass data that will enable EFSA to assess whether the use of the food is not nutritionally disadvantageous for the consumer".*

Vote taken: Unanimity.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation laying down administrative and scientific requirements concerning traditional foods from third countries in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods.

The draft Commission Regulation has been published on 19 July 2017 on the better regulation portal for a 4-week public consultation (https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-3649042_en).
The period of public consultation ended on 16 August 2017.

In total, three comments were submitted in the last days of the public consultation. In addition, comments by another stakeholder were made under the consultation of the draft Implementing Regulation laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods.

All the comments were received from business associations, in particular from the following business associations: FDE (FoodDrinkEurope), FSE (Food Supplements Europe), ELC (EU Specialty Food Ingredients) and IPIFF (International Platform of Insects for Food and Feed).

The comments relate mainly to the following issues (not exhaustive) :

- The need to refer to EFSA guidance

- The need to keep 2 January 2020 as the deadline for the transitional measures
- The need to provide raw data of the individual unpublished and published studies
- The need to require data to enable a risk assessment
- The need to include the post-market monitoring requirements in the proposal
- The need to include examples of non-valid dossiers.

The Commission's representative provided the following information :

The EFSA guidance on novel foods cannot be referred to in the draft Implementing Regulation as the Commission does not have a formal control on it.

Regarding the transitional measures, the new novel food regulation provided for a transitional period allowing food business operators to continue placing products on the market without such EU authorisation until their request for placing the product on the market has been decided upon. The Commission has been empowered in the novel food Regulation adopted on 25 November 2015 to set the deadline until such notifications will be considered for no later than 2 January 2020. The Commission has set the deadline for traditional foods from third countries in the draft implementing Regulation for 1 January 2019. This deadline takes account of the legitimate rights of food business operators as it ensures that the food business operators gain legal certainty about the legality of their product in the market as quickly as possible. Secondly, food business operators were aware of the requirements of a notification being applicable to them as of 1 January 2018 already with the adoption of the novel food Regulation on 25 November 2015 and therefore could prepare for the changes introduced by the new regime. The deadline set in the implementing act grants them one more year to finalise their notifications.

The need to provide raw data and required data to enable a risk assessment were considered not to be in line with what it is required to demonstrate the history of safe use of the traditional foods from third countries.

The draft Implementing Regulation submitted for public consultation has been amended to take into account the comments made during that consultation period. The amended draft Implementing Regulation was submitted to the Committee for opinion.

A Member State made the following statements: *"The data provided in the notification or application to enable the assessment of the history of safe use must encompass data that will enable to assess whether the use of the food is not nutritionally disadvantageous for the consumer" and "If a traditional food from a third country is intended for the general population or a particular group of that population, but that it cannot be excluded that it would be also consumed by other groups of the population for which there could be safety concerns (children for instance), this point can be the object of duly reasoned safety objections. As a consequence, the applicant should address those objections on the basis of additional data in terms of the composition of the product or the history of safe use for those particular groups. If the applicant cannot demonstrate the safety those particular groups based on these requirements, the applicant can apply under Article 10 of the basic act".*

Vote taken: Unanimity.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision authorising the placing on the market of UV-treated mushrooms with increased levels of vitamin D_2 as a novel food under Regulation (EC) No 258/97 of the European Parliament and of the Council.

The Commission presented the proposal Commission Implementing Decision (EU) authorising the placing on the market of UV-treated mushrooms as a novel food and the Committee delivered its opinion with no objections.

Vote taken: Unanimity.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision authorising an extension of use of Chia seeds (*Salvia hispanica*) as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council.

The Commission presented the proposal Commission Implementing Decision (EU) authorising an extension of use of Chia seeds (Salvia hispanica) as a novel food ingredient and the Committee delivered its opinion with no objections.

Vote taken: Unanimity.

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of Thaumatin (E 957) as a flavour enhancer in certain food categories.

The Commission received an application requesting an authorisation to use thaumatin (E 957) as a flavour enhancer in several food categories of Annex II to Regulation (EC) No 1333/2008.

In 2015, the European Food Safety Authority issued a scientific opinion on the safety of the proposed extensions of use and use levels of thaumatin (E 957) as a food additive, and concluded that those would not represent a safety concern.

Therefore, it is appropriate to authorise the use of thaumatin (E 957) as a flavour enhancer at a maximum level of 5 mg/kg in products of food categories 12.6 ‘Sauces’ and 15.1 ‘Potato-, cereal-, flour- or starch-based snacks’ at a maximum level of 5 mg/kg in each food category and to amend Annex II to Regulation (EC) No 1333/2008 accordingly.

Vote taken: Unanimity.

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending the Annex to Regulation (EU) No 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards specifications for Polyvinyl alcohol-polyethylene glycol-graft-co-polymer (E 1209).

The Commission received an application for the amendment of specifications concerning the food additive Polyvinyl alcohol-polyethylene glycol graft-co-polymer (E 1209).

The European Food Safety Authority evaluated the safety of an amendment of the specifications for that food additive as requested and concluded that it would not be of a safety concern. However, EFSA noted that the analytical results provided were consistently and considerably lower (up to 360 mg/kg) than the proposed level of 620 mg/kg for ethylene glycol individually or in combination with diethylene glycol in the EU specifications for E 1209.

Consequently, it is appropriate to amend the levels of the impurities ethylene glycol and diethylene glycol in the food additive polyvinyl alcohol-polyethylene glycol-graft-co-polymer (E 1209) to 'not more than 400 mg/kg for ethylene glycol individually or in combination with diethylene glycol' and the Annex to Regulation (EU) No 231/2012 should be amended accordingly.

Vote taken: Unanimity.

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) amending and correcting Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards certain flavouring substances.

This measure concerns the lifting of the status of "under evaluation" for a number of flavourings currently under evaluation after the EFSA assessment and also the correction of the names concerning the identification of two other flavouring substances.

Vote taken: Unanimity.

B.10 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of polyglycerol polyricinoleate (E 476) in emulsified sauces.

The Commission received an application requesting an authorisation of the use of polyglycerol polyricinoleate (E 476) as an emulsifier in emulsified sauces. According to Annex II to Regulation (EC) No 1333/2008 polyglycerol polyricinoleate (E 476) is an already authorised food additive in food category 12.6 ‘Sauces’ (at a maximum level of 4 000 mg/kg), but only for dressings.

On 24 March 2017, the Authority delivered a Scientific Opinion on the re-evaluation of polyglycerol polyricinoleate (E 476), which also included an assessment of safety of the requested extension of use of polyglycerol polyricinoleate (E 476) in all emulsified sauces. EFSA concluded that polyglycerol polyricinoleate (E 476) as a food additive would not be of safety concern if used at the permitted or reported use and use levels. In addition, EFSA concluded that the extension of use for polyglycerol polyricinoleate (E 476) in emulsified sauces is not of safety concern.

Therefore, it is appropriate to authorise the use of polyglycerol polyricinolate (E 476) as an emulsifier in emulsified sauces, including dressings, in food category 12.6 'Sauces' (at a maximum level of 4 000 mg/kg) and to amend Annex II to Regulation (EC) No 1333/2008 accordingly.

Vote taken: Unanimity.

B.11 Exchange of views and possible opinion of the Committee on a draft Implementing Decision (EU) authorising the placing on the market of hydroxytyrosol as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council.

Several Member States voted against or abstained citing disagreement with the use of labelling on the product to ensure that certain population groups which are excluded from the application and the risk assessment do not consume the product. The Member States voting against or abstaining consider that the safety of novel foods must be established for the entire population regardless of the intended uses in the application.

Vote taken: Favourable opinion.

B.12 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation on detailed rules on the maximum residue limit to be considered for control purposes for foodstuffs derived from animals which have been treated under Article 11 of Directive 2001/82/EC.

The Commission's representative introduced the draft and presented its contents, clarifying that the proposal aims at giving legal certainty on residues in food from animals treated under the cascade system, laid down in Art. 11 of Dir. 2001/82/EC. The cascade can only be used in exceptional cases, when no authorised veterinary medicinal product (VMP) is available for a specific species in the Member State (MS). Currently no MRLs are defined for the residues in the food of animal origin, originating from such uses and it is expected that the establishment of clear MRLs will result in the application of proper waiting times or good practices, to ensure that residues remain below safe limits. As cascade uses are exceptional, they should be considered as minor contributors to the chronic exposure. By selecting the lowest MRL, established for other tissues and/or other species, sufficient guarantees are available for ensuring consumer safety.

The Commission's representative presented an overview of the Member States' comments, which were received in advance of the meeting. It clarified that residues of coccidiostats in food of animal origin in case of cross-contamination of feed, regulated under Reg. (EC) No 124/2009 and therapeutic and zootechnical treatments, foreseen in Directive 96/22/EC, fall outside the scope of the proposal. Furthermore the restrictions specified in Table 1 of the annex to Reg. (EU) No 37/2010 equally apply to cascade uses.

Several Member States indicated to be in favour of removing bees from the scope of the proposal. However, as bees are a food producing species, they fall under the scope of Art. 11 of Dir. 2001/82/EC on cascade uses. Therefore already today treatments of bees under the cascade are authorised. The current proposal only provides legal certainty on MRLs for veterinary medicinal products treatments, which are already authorised in specific cases. As honey is less consumed than other animal origin commodities, MRLs that are considered safe for those commodities, will certainly also be safe for honey and no ADI exceedances will occur.

Quite some concerns were raised, that this proposal will open the EU market for imported products, produced under animal husbandry standards, not comparable to EU standards. This concern was mainly raised in relation to the inclusion of honey in the scope of this proposal. The use of the cascade applies to uses in EU Member States, in cases in the Member States no authorised veterinary medicinal products is available, in order to protect animal health. In the EU no information is available on authorisations in third countries and also fewer guarantees are available on the system of authorisation, prescription, dispensation, record keeping, traceability and animal identification of the third country. Because these control mechanisms are not available to the EU for imported products, it needs to be further discussed whether the cascade MRLs should be restricted to EU production.

Certain Member States asked to retain the vote until the final agreement will be reached on the new Regulation on veterinary medicinal products. However as in the new veterinary medicinal products proposal, which is currently under discussion, no changes are included that will impact on the cascade MRLs, there is no need to postpone the proposal on the cascade MRLs.

Under the public feedback mechanism, tree comments were received :

FEEDM (the Fédération Européenne des Emaballeurs et Distributeurs the miel) supports the proposal as it solves the loophole in the EU legislation regarding animal welfare, as it guarantees consumer protection by selecting the lowest MRL and because it provides legal certainty regarding the MRLs.
The COAG (Coordinadora de Organizaciones de Agricultores y Ganaderos - Sector Apícola) commented that this proposal will allow the use of antimicrobial drugs on bees in the EU. However, as bees are a food producing species, they already now fall under the scope of Art. 11 of Directive 2001/82 on cascade uses. This proposal merely allows the uniform application of MRLs. The organisation fears that this proposal will facilitate the import of honey with residues of antimicrobials from third countries and that this honey will not be subject to the same requirements as the EU honey. As indicated above, the discussion on whether the cascades MRLs would apply to imported products, will be continued. Also concerns were raised regarding consumer

risks related to VMP residues in honey. As honey is less consumed than other animal origin commodities, MRLs that are considered safe for those commodities, will also be safe for honey.

The Cooperativas Agro-alimentarias de España, welcomes the proposal as consumer safety is guaranteed by selecting the lowest MRL and because legal certainty is provided regarding the MRLs for cascade uses.

In view of the various concerns raised by the Member States, no vote was taken on the proposal and it was decided to continue the discussion at the next expert meeting on residues of veterinary medicines (date to be determined in January 2018) prior to a possible vote at the February meeting of the PAFF Committee.

Vote postponed

M.01 A.O.B.

No issues raised under this agenda item.