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 25 NOVEMBER 2016

(Section Toxicological Safety of the Food Chain)

CIRCABC Link: *https://circabc.europa.eu/w/browse/89043dca-40f3-4d02-9729-831b2b619a70*

A.01 Exchange of views and possible endorsement of a draft Commission Recommendation on the monitoring of mineral oil hydrocarbons in food and materials and articles intended to come into contact with food.

A monitoring Recommendation related to mineral oil hydrocarbons in food and food contact materials was presented. This monitoring exercise covers a wide variety of food commodities as well as the food contact materials. When mineral oil hydrocarbons are detected, a follow-up investigation into the possible source will be triggered. The monitoring exercise will be on-going in 2017 and 2018. The results will be used to study possible future risk management options.

Member States expressed the importance of the technical guidance document that is under development by the JRC - European Union Reference Laboratory for food contact materials. The Commission reminded the Member States to actively participate in the relevant task force at least by sending in their questions and needs so that the guidance document can be developed rapidly and contain information that is relevant for all involved parties.

The draft proposal was unanimously endorsed.

A.02 Exchange of views and approval of the 2016 national residue monitoring plans for residues of veterinary medicinal products in accordance with Directive 96/23/EC.

The Commission informed the Member States that the Member States' residue monitoring plans for animals and animal products had been evaluated by DG SANTE as foreseen by Directive 96/23/EC. This evaluation includes the review of the plans by the European Union Reference Laboratories. The Commission recommends the approval of all 28 Member States' residue monitoring plans for 2016.

This year's exercise focused on the scope of the residue monitoring plans with the aim to identify the risk criteria used by Member States for the selection of substances to be included or excluded from the monitoring. The results of this year's scrutiny of evaluations should feed information into the imminent review of Directive 96/23/EC.

As foreseen in Article 8 of Directive 96/23/EC, Member States now have 10 working days to inform the Commission of any comments. In case no comments are received on 12 December 2016, the plans shall be deemed to be approved. The Commission will approve the plans through the residue application by changing the status from "accepted" to "approved".

A.03 Exchange of views on envisaged measures as regards maximum levels of mercury in foodstuffs.

The three main aspects of the technical discussion on the review of the maximum levels for mercury were discussed with the Member States : the further differentiation of the maximum levels for fish, the increased awareness of the food consumption advice and the compilation of all legal standards for mercury in food in a single legislative act. Further technical aspects will be discussed at expert level.

Regarding the further subdivision of the two existing maximum levels to four groups of fish species thus aligning the legal situation to the maximum number of weekly servings mentioned in EFSA's risk benefit opinion, Member States by large agreed to the principle although some expressed concerns by the creation of a group of 2 mg/kg for top predatory fish species.

On the increased awareness and active distribution of specific food consumption advice developed on basis on the national fish consumption pattern, most Member States agreed on the importance of specific national food consumption advice. A number of Member States however expressed their concerns on the modalities related to the active distribution towards the consumer.

The concentration of all legal standards for mercury in the legal framework of contaminants in food was welcomed by all but one Member State.

A.04 Feedback from discussions from the Expert Committee Agricultural Contaminants and industrial and Environmental contaminants (details to follow).

a) Regulatory follow-up as regards the presence of opium alkaloids in poppy seeds

EFSA adopted in 2011 an opinion on the risks for public health related to the presence of opium alkaloids in poppy seeds.

As regulatory follow-up, Commission Recommendation (EU) 2014/662 of 10 September 2014 on good practices to prevent and to reduce the presence of opium alkaloids in poppy seeds and poppy seed products was adopted.

Following RASFF notifications on the presence of morphine in poppy seeds the discussion on the possible setting of maximum levels has taken place. Following discussions at the Expert Committee meeting, following actions and conclusions were agreed :

- Elaborating provisions as regards sampling and analysis of opium alkaloids in poppy seeds. For the analytical aspects (performance criteria) the European Union Reference Laboratory (EURL) shall provide support to the Commission and shall possibly organise a proficiency test.

- The Commission has requested EFSA to provide an update to the scientific opinion as regards the toxicity (pharmacological potency)/relevance of the opium alkaloids codeine, thebaine, noscapine, papaverine and oripaverine relative to morphine.

- Member States and food business operators are requested to continue to provide further monitoring data to the EFSA database on the presence of morphine and other opium alkaloids in poppy seeds and foods containing poppy seeds.

- Awaiting the EFSA opinion on the opium alkaloids other than morphine, a target level of 10 mg/kg for the presence of morphine in poppy seed placed on the market destined for the final consumer was agreed (‘placing on the market’ and ‘final consumer’ as defined in article 2 of regulation (EC) N° 178/2002).
This target level is proposed to be applied as well to poppy seeds at any stage of the food chain if not labelled in an appropriate way indicating the need to subject the poppy seeds to a physical treatment to reduce the opium alkaloid content before human consumption or use as an ingredient in foodstuffs (physical treatments are described in Commission Recommendation (EU) 2014/662).

b) Clarification "destined for direct human consumption"

In Commission Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs, maximum levels are established for foods for direct human consumption.

For certain contaminants higher maximum levels are applicable to foods to be further processed than for final consumer products as the processing can result in a reduction of the contamination level. It is the responsibility of the food business operator to ensure that the final consumer products placed on the market comply with the stricter maximum level.

As it cannot be foreseen what treatments the consumer shall perform on purchased foods in retail to prepare food at home and to which extent these home treatments shall reduce the presence of contaminants in the prepared foods for direct consumption, it is appropriate to apply the maximum levels for foods destined for direct human consumption to foods placed on the market for the final consumer (in retail sale).

A.05 Exchange of views on the overall procedure to follow for flavouring substances under evaluation when a safety concern on the representative substance is identified by EFSA.

The Working Group on flavourings continues to progress on the topic. It will report to the PAFF Committee at the next meeting.

A.06 Feedback from the working group flavourings on the follow-up to the EFSA Opinion on quinine and its salts.

After examination of the EFSA "Scientific Opinion on Flavouring Group Evaluation 35, Revision 1 (FGE.35Rev1), three quinine salts from the Priority list from chemical group 30" of September 2015 [1] , it is considered that the current conditions of use as flavouring substances of quinine and its salts as reflected in Regulation 1334/2008, which include *inter alia* maximum limits in identified food categories, do not need to be modified.

[1] EFSA Journal 2015;13(9):4245

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) amending Annex II to Regulation (EU) No 1333/2008 of the European Parliament and of the Council as regards the use of Steviol glycosides (E 960) as a sweetener in certain energy-reduced confectionery products.

The Commission received an application for authorisation of the use of steviol glycosides (E 960) as a sweetener in certain energy-reduced confectionery products.

Steviol glycosides are non-caloric sweet-tasting constituents and may be used to replace caloric sugars in certain confectionery products, thus reducing their caloric content and offering consumers energy-reduced products, in accordance with Article 7 of Regulation (EC) No 1333/2008.

In 2010, the European Food Safety Authority evaluated the safety of steviol glycosides and established an Acceptable Daily Intake (ADI) of 4 mg/kg body weight/day, expressed as steviol equivalents. In 2015 the Authority revised the exposure assessment of steviol glycosides and foods of category 05.2. 'Other confectionery including breath freshening microsweets' were not identified as one of the main food categories contributing to exposure to steviol glycosides (E 960).

Considering that the exposure estimates are below the ADI for all age groups the proposed uses and use levels of steviol glycosides (E 960) as a sweetener are not of a safety concern.

Therefore, it is appropriate to authorise the use of steviol glycosides (E 960) as a sweetener in certain energy-reduced confectionery products in food subcategory 05.2 and to amend Annex II to Regulation (EC) No 1333/2008 accordingly.

Vote taken: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) amending 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 Basic methacrylate copolymer (E 1205).

The Commission received a request for an amendment of the specifications concerning the food additive basic methacrylate copolymer (E 1205).
The applicant requested the definition of the food additive to be amended with regard to the short description of the manufacturing process due to a modernization of the manufacturing process. Following a thorough review of the particle size in the current specification, the applicant has requested a change in the particle size of the powder.

The European Food Safety Authority ('the Authority') adopted an opinion on the safety of the proposed amendment in which it concluded the proposed amendments to the specifications of the food additive Basic methacrylate copolymer (E 1205) are not of a safety concern.
Regulation (EU) No 231/2012 should therefore be amended accordingly.

One Member State asked why it was not specified that nano-materials are not present in the additive. The Commission explained it is not the intention of the applicant to produce the material in nanoscale. Furthermore 90 % of the particle size distribution is above the 3 μm with most of the material below 50 μm, possible presence would therefore only be negligible.

Vote taken: Favourable opinion.

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 certain flavouring substances.

The Commission representative presented the draft Regulation.
It also reported about the comments received under the publication for feedback mechanism included in the Better Regulation Portal, to which the draft text had been published. When the period for comments had ended, there were 21 comments submitted. There were comments from the flavouring producers associations (IOFI, EFFA, 7 national associations (DVAI (DEU), AISPEC (ITA), NEA (NLD), DFO (DNK), the UK National flavouring association, SNIIA (FRA), AEFAA (ESP), and Aroma (BEL). They are all members of EFFA. There were five comments from EU flavouring producing companies (Robertet, Symrise, Vögele, Kerry ingredients, Mane). They are also members of EFFA. There was one comment from a company from outside the EU, the Swiss flavouring company Givaudan, also member of EFFA. There were four comments from the food industry (the European association Fooddrink Europe, the European association of producers of snacks, the German food

industry association BLL, and the French food association ANIA. There was also one comment from the American association of producers of flavourings, FEMA.

None of these comments provided substantial new data or information that was not considered in preparation of the draft Regulation.

The substances being the object of the draft measure remain in the Union list with a footnote 1 "under evaluation by EFSA" and their uses and their levels are therefore maintained. These uses and levels are those reported by industry.

The amount of time necessary for EFSA to carry out a complete evaluation of a group of existing flavourings like this one involves, the consideration of the genotoxicity aspects of the substances to be examined in a first opinion on this issue and then, afterwards, if appropriate, apply the so called EFSA CEF procedure in one or several other EFSA opinions. It is therefore likely that it will take many months, possibly significantly more than a year to complete the assessments for all of these 20 substances.

The industry has offered and submitted a wide and complex range of toxicological studies which are under assessment by EFSA. Not taking any measure now would mean that the current legal situation of no restrictions in any food for any of the 20 substances would remain and, therefore, further uses could be added to, for example, foods for infants or other food categories, or the current reported levels of use could be increased for substances of which the safety still needs to be confirmed.

As regards the potential conflict with other assessments bodies such as JECFA, the JECFA assessment was published in 2004 while the EFSA is of 2014. EFSA took account of the JECFA assessment and also took into account additional data on the safety of these substances available after 2004, together with the data produced and submitted by industry and the IARC evaluation of 2013.

According to the EFSA opinion, four substances in this group have not been evaluated by JECFA: FL nos: 05.081, 05.186, 05.194 and 05.196.

As regards the transition period, the substances remain in the Union List and the reported uses are maintained. The transition period foreseen in Article 1 and the period before adoption of the measure provide enough time to adapt the already existing documentation accompanying the flavourings sold singly or mixed to the requirements of Article 15 g of Regulation 1334/2008.

One Member State was of the opinion that, following the EFSA scientific opinion and based on the precautionary principle, measures must be taken in a way to protect the most vulnerable population group, the children. Therefore, food categories that contribute more significantly to the intake of the substances in children should be excluded, namely food categories 1 (dairy products), 7 (baked goods) and 14.1 (non-alcoholic beverages).

Another Member State considered that substances such as the ones included in this measure should not have been included in the Union list when it was adopted back in

2012 (Regulation (EU) No. 872/2012). This Member State considers this measure however as a step in the right direction.

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Regulation setting maximum levels for certain contaminants in food repealing Commission Regulation (EC) No 1881/2006.

As the internal Commission consultation procedure is not yet finalised, the point is postponed to next meeting of the Standing Committee.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food.

The Regulation (EU) No 10/2011 sets out rules on the composition and testing of Plastic food contact materials. The Regulation also includes a Union list which authorises approximately 1000 substances that can be used to manufacture plastic food contact materials. On the basis of newly available EFSA opinions new substances should be added to this list. Also a limit on nickel in Annex II would need to be introduced on the basis of an EFSA opinion, and editorial changes to table 3 in Annex III to the Regulation and Point (8)(iii) of Annex IV would need to be made.

A draft Commission Regulation was presented to the Committee to achieve these objectives.

Vote taken: Favourable opinion.

C.01 Exchange of views of the Committee on a draft Commission Regulation amending Regulation (EC) 1881/2006 as regards maximum levels of hydrocyanic acid in certain raw apricot kernels.

The Scientific Panel on Contaminants in the Food Chain (CONTAM) of the European Food Safety Authority (EFSA) adopted a scientific opinion on acute health risks related to the presence of cyanogenic glycosides in raw apricot kernels and products derived from raw apricot kernels.

Amygdalin is the major cyanogenic glycoside present in unprocessed apricot kernels and is degraded to hydrocyanic acid (cyanide) by chewing. Cyanide is of high acute toxicity in humans. An acute reference dose (ARfD) of 20 µg/kg bw was derived by the CONTAM Panel for assessing the risks associated with the presence of cyanogenic glycosides in unprocessed whole, ground, milled, cracked, chopped apricot kernels. Taking into account the reported levels of cyanogenic glycosides in unprocessed apricot kernels, the ARfD would be exceeded already by consumption of one small kernel in toddlers, while adults could consume three small kernels. However, consumption of less than half of a large kernel could already exceed the ARfD in adults.

Therefore the draft Regulation provides for a strict maximum level of 20 mg/kg for the presence of hydrocyanic acid in unprocessed whole, ground, milled, cracked, chopped apricot kernels and products derived from raw apricot kernels placed on the market for the final consumer.

The Committee was also informed that EFSA has been requested by the Commission to assess the applicability of the ARfD established for cyanogenic glycosides in unprocessed apricot kernels for other foods in which cyanogenic glycosides are present.

No objections were raised on the proposed provisions. Some editorial comments were made which shall be taken into account.

C.02 Exchange of views of the Committee on a draft Commission Regulation amending Regulation (EC) 1881/2006 as regards maximum levels of 3-MCPD, 3-MCPD fatty acid esters and glycidyl esters in certain foods.

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.

3-Monochloropropane-1,2-diol (3-MCPD)- and 2-monochloropropane-1,3-diol (2-MCPD) and their esters and glycidyl esters are food contaminants found at highest levels in refined vegetable oils. 3- and 2-MCPD esters and glycidyl esters are hydrolysed to their respective free forms in the gastrointestinal tract.

The CONTAM Panel established for 3-MCPD a Tolerable Daily Intake (TDI) of 0.8 µg/kg bw per day and concluded that this TDI constitutes a group TDI for 3-MCPD and its fatty acid esters (expressed as MCPD equivalents). No health-based guidance value could be established for 2-MCPD due to insufficient toxicological information. Finally the CONTAM Panel concluded that glycidol is a genotoxic and carcinogenic compound.

The CONTAM Panel concluded that the estimated exposure to 3-MCPD of infants receiving only formula was above the group TDI, which could be exceeded up to fourfold. For 2-MCPD and 2-MCPD fatty acid esters, as no TDI could be established, it was not possible to undertake a risk characterisation. 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.

It is therefore proposed to establish a strict maximum level for the presence of 3-MCPD and its fatty acid esters and glycidyl fatty acid esters in vegetable oils and fats intended for direct human consumption or use as an ingredient in food and in infant formula and follow-on formula, taking into account what is currently achievable by applying good practices. However there is a need to further reduce the presence of 3-MCPD and its fatty acid esters and glycidyl fatty acid esters in infant formula and

follow-on formula and therefore it is appropriate to establish stricter maximum levels applicable as from 1 July 2019, enabling food business operators to perform the necessary changes to the production to achieve this lower level.

The Committee was informed of the content of the summary report of the 83rd Joint FAO/WHO Expert Committee on Food Additives (JECFA) (meeting held in Rome from 8 to 17 November 2016) in respect to the assessments of 3-MCPD esters and glycidyl fatty acid esters. Differences were identified in the application of benchmark dose modelling for the dose-response analysis approaches applied by JECFA and by the CONTAM Panel. As a result of these different approaches, an important scientific divergence was identified in particular in the tolerable daily intake levels established for 3-MCPD esters by the CONTAM Panel (0.8 µg/kg bw per day) and JECFA (4 µg/kg bw per day).

The Committee was informed that the CONTAM Panel, upon request from the European Commission agreed that a detailed analysis of the identified scientific divergences is warranted with the aim to conclude whether an update of the CONTAM opinion on the risks for human health related to the presence of 3- and 2-MCPD, and their fatty acid esters, and glycidyl fatty acid esters is deemed necessary.

Therefore it is appropriate to await the outcome of the analysis of the CONTAM Panel, expected by the end of January 2017, before concluding on the appropriate regulatory measures on the presence of 3-MCPD and its fatty acid esters and glycidyl fatty acid esters in vegetable oils and fats intended for direct human consumption or use as an ingredient in food and in infant formula and follow-on formula.

C.03 Exchange of views of the Committee on a draft Commission Regulation on the application of codes of good practice to reduce the presence of acrylamide in food.

The Scientific Panel on Contaminants in the Food Chain (CONTAM) of the European Food Safety Authority (EFSA) adopted an opinion on acrylamide in food. T he CONTAM Panel concluded that although the available human studies have not demonstrated that acrylamide is a human carcinogen, the Margin of Exposure (MOEs) based on the current levels of dietary exposure to acrylamide across surveys and age groups indicate a concern with respect to carcinogenic effects.

It is therefore appropriate to reduce the presence of acrylamide as much as possible by applying measures to prevent and reduce formation of acrylamide in specific manufacturing practices. These measures are contained in Codes of Practice. Codes of Practice have been developed for potato based products, cereal based products, coffee and coffee substitutes and baby food and for plant bakery products. Specific codes of practices have been elaborated for food business operators who place on the market directly to the consumer ready-to-eat food.

The draft Regulation makes the application of the Codes of Practice mandatory and food business operators have to establish an ongoing monitoring programme as part of their established Food Safety Management Systems to analyse their food products for the presence of acrylamide. Data from the programme should be used to confirm that,

via the application of the obligatory requirements within the Code of Practice, they are successfully managing acrylamide levels. Specific levels are set to be used by food business operators as benchmark to verify the effectiveness of their controls. The levels to be used as benchmark shall be established taken into account recent occurrence data and shall be regularly reviewed taking into account the continuous reduction of acrylamide in food through the mandatory application of the Codes of Practice Also the Codes of practice shall be regularly reviewed to take into account the developments in new mitigation measures to further reduce the presence of acrylamide in food.

To ensure that the Codes of Practice are applied by the food business operators and that food business operators fulfil their obligations to check the effectiveness of the mitigation measures to reduce the presence of acrylamide in food by taking sufficient samples and analyse for the presence of acrylamide, the Member States should put in place effective controls.

The large majority of the Committee supported the measures and stressed the need to have these measures adopted without delay. While in favour of the envisaged measures, a number of Member States are of the opinion that it is necessary for certain foods/food categories to establish maximum levels for acrylamide, complementary to the envisaged measures.

The Commission informed the Committee that the measures are still in the Commission's internal consultation process and that this measure shall be subject to feedback from citizens and stakeholders (https://ec.europa.eu/info/law/better-regulation/share-your-views_en).

C.04 Exchange of views of the Committee on a draft Commission Regulation (EU) amending Annex II to Regulation (EU) No 1333/2008 of the European Parliament and of the Council as regards the use of phosphoric acid–phosphates–di–tri–and polyphosphates (E 338-452) in certain meat preparations.

The proposed draft Regulation was presented. The draft concerns an extension of use of phosphates in certain Czech meat preparations (*Bílá klobása, Vinná klobása, Sváteční klobása and Syrová klobása).*
The Commission representative informed that the draft is subject to the feedback mechanisms before it is presented for a possible opinion of the Committee.

C.05 Exchange of views of the Committee on a draft Commission Regulation (EU) amending Annex III to Regulation (EU) No 1333/2008 of the European Parliament and of the Council as regards the use of butane (E 943a), isobutane (E 943b) and propane (E 944) in colour preparations.

The proposed draft Regulation was presented. The draft concerns the authorisation of butane (E 943a), isobutane (E 943b) and propane (E 944) as propellants in colour preparations of group II and group III, as defined in Part C of Annex II to Regulation (EC) No 1333/2008.

C.06 Exchange of views of the Committee on a draft Commission Regulation (EU) amending Annex II to Regulation (EU) No 1333/2008 of the European Parliament and of the Council as regards the use of nitrites (E 249 – 250) in golonka peklowana.

The proposed draft Regulation was presented. The draft concerns an extension of use of nitrites in Polish meat preparation *golonka peklowana*. The Commission representative informed that the draft is subject to the feedback mechanisms before it is presented for a possible opinion of the Committee.

M.01 A.O.B.

No issues raised under this agenda item.