EUROPEAN COMMISSION

Health and Food Safety Directorate General

sante.ddg2.g.5(2019)2850013

SUMMARY REPORT OF THE STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED HELD IN BRUSSELS ON 29 MARCH 2019

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

CIRCABC Link: *https://circabc.europa.eu/w/browse/4dda19a0-eaaa-4ef8-a482-4427888ea66a*

A.01 EFSA Report for 2017 on the results from the monitoring of veterinary medicinal product residues and other substances in live animals and animal products.

The Commission informed Member States that the report has now been finalised by EFSA and that it will be published soon. Portugal commented that some figures in the report do not correctly reflect their National Monitoring Plan (NMP), as Portugal analysed more samples than those indicated in the report. This difference is due to the difficulties which Portugal experienced for reporting of the monitoring data to EFSA in the SSD2 format. In addition, at the time of reporting not all the results of Portugal were available yet.

Therefore, as a way to correctly reflect their performance, Portugal proposed to change the wording "analysed samples" in the report to "reported samples" and "did not achieve the minimum sampling frequency for…" to "did not report the minimum sampling frequency for. Furthermore Portugal requested to add a sentence to the report, stating that it summarises results from samples which are reported by the Member States, which may not represent the real outcome of their National RMP. The Commission explained that it was not possible for EFSA to redraft the report, taking into account reporting errors of the Member States. However, EFSA summarised the comments or feedback in Appendix G of the report. The re-drafting suggestions from Portugal were received too late stage, and could unfortunately not be taken into account anymore. The Commission encouraged Member States to pay special attention and avoid reporting errors when reporting their 2018 monitoring data.

A.02 Feedback on the recent work of the Expert Group on Food Contact Materials.

The Committee was updated concerning the work of the Expert Working Group on Food Contact Materials (FCMs). The most recent meeting took place 25 – 26 February. The working group had discussed the next amendment to Regulation (EU) No 10/2011, in particular on a consolidation of migration limits for metals under Annex 2 to the Regulation, as well as a number of substances. The European Food Safety Authority made a presentation on its ongoing re-assessment on phthalates. The draft opinion is subject to a public consultation until 14 April. Thereafter, the opinion will be finalised and the Commission will act, if necessary, on this new opinion. Additional information will also be sought by the Commission from the industry as regards the uses of phthalates in FCMs. Additional EFSA mandates include

prioritisation of the possible setting of specific migration limits (SMLs) for substances for which no SML presently exists, as well as re-assessment of the authorisation of FCM 96 (wood flour and fibres, untreated).

Concerning the ongoing FCM evaluation, Member States have been updated on progress including the launch of the online public consultation. There was also a discussion amongst experts on the positive authorised list approach to regulating FCM substances. The output from this is available on DG SANTE website and will feed into the evaluation process. A draft version of the Recommendation on a coordinated control plan was also finalised. Lastly certain specific matters relevant for plastic recycling were discussed, including potential matters regarding the control of the quality of input materials, and the authorisation of closed loop and HDPE recycling processes.

A.03 Exchange of views on the review of Commission Implementing Regulation (EU) 2016/6 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 (foreseen to be reviewed by 30 June 2019).

Implementing Regulation (EU) 2016/6 provides for a review of its provisions before 30 June 2019, after the results of sampling and analysis on the presence of radioactivity of feed and food from the seventh and eighth growing season (2017 and 2018) after the accident are available.

The Committee was informed of the request from Japanese authorities for a complete lifting of the measures. In addition, an update was given about the current status of the nuclear power plant and of the ongoing discussions in Japan as regards the options for a disposal of the contaminated cooling water.

Following an exchange of views, a majority of the delegations expressed to be in favour of a further gradual alleviation of the measures, applying the criteria used for the previous review, and not being in favour of a complete lifting of these. A few delegations indicated to be in a position to support the request from japan for a complete lifting of the measures.

The Commission's representative committed to share the outcome of the detailed examination of the monitoring results via CIRCABC and, in case of a need, to organise a specific meeting to discuss these in detail, in view of the finalisation of a draft Regulation for possible opinion at the next meeting of the Committee in June.

A.04 Feedback and exchange of views on topics discussed in recent meetings of the Working Groups on agricultural contaminants and industrial and environmental contaminants in food.

- maximum levels for pyrrolizidine alkaloids

Following a targeted stakeholder consultation, the discussion at technical level on maximum levels for pyrrolizidine alkaloids in tea, herbal infusions, food supplements containing herbal ingredients, pollen-based food supplements, pollen and pollen products, herbs and certain spices is close to finalisation. More discussion in the working group is needed on herbs, possibly food supplements containing herbal ingredients, and certain analytical aspects.

The possible setting of a maximum level for pyrrolizidine alkaloids in honey was raised. The Commission representative indicated that, while it had been initially

considered, it was finally decided not to set a maximum level for honey at this stage; however, it is not excluded that a maximum level or pyrrolizidine alkaloids in honey shall be set in the future.

- maximum levels for ergot and ergot alkaloids

Following a targeted stakeholder consultation, the discussion on maximum levels for ergot alkaloids in grains intended for direct human consumption and milling products of barley, wheat, spelt, rye and oats is close to finalisation. Different maximum levels are under discussion for milling products containing a high ash content compared to the milling products with lower ash content. Also a strict maximum level for processed cereal based food for infant and young children is under discussion.

In addition, a lowering of the maximum level for ergot sclerotia is under consideration.

- maximum levels for tropane alkaloids

Following a targeted stakeholder consultation, the discussion at technical level on maximum levels for tropane alkaloids in processed cereal-based foods and baby foods for infants and young children containing maize, grains and milling products of millet, buckwheat, maize and sorghum, popcorn and herbal infusions is close to finalisation..

- grayanotoxins in honey

In the meeting of the Working group it was concluded that there is no need to take immediate regulatory action at Union level. Measures taken at national levels appear to be effective and do avoid poisoning cases in the EU.

A delegation indicated that it would be appropriate to request EFSA to perform a risk assessment in order to be able to conclude on the need to take additional risk management measures at EU level.

The Commission's representative committed to ask EFSA to perform a risk assessment.

- maximum levels for glycidyl fatty acid esters and 3-MCPD fatty acid esters

Following a targeted stakeholder consultation, the discussion at technical level on maximum levels for glycidyl fatty acid esters in fish oils and oils from other marine organisms and in young-child formula (in addition to the already established maximum levels), for 3-MCPD fatty acid esters in vegetable oils and fats, fish oils and oils from other marine organisms in infant formula, follow-on formula, food for special medical purposes intended for infants and young children and young child formula, is close to finalisation. More discussion in the working group is needed on unrefined vegetable oils and olive oil.

A short exchange of views took place. A few delegations indicated to prefer for 3-MCPD esters a single maximum level in vegetable oils instead of the currently proposed “split level”, i.e. a lower level for certain named vegetable oils while a higher level for other vegetable oils. The Commission representative indicated that this issue has been discussed very extensively in the working group and that a large majority is in favour of the current proposed “split-level”.

- maximum levels for perchlorate

Following a targeted stakeholder consultation, the discussion at technical level on maximum levels for perchlorate in fruits and vegetables, tea, herbal and fruit

infusions, infant formula, follow-on formula, babyfood and processed cereal-based food, has been finalised.

A draft Regulation shall be submitted for opinion to the Committee once the internal Commission consultation has been completed.

- maximum levels for acrylamide

A targeted stakeholder consultation took place on possible maximum levels for acrylamide in biscuits and rusks for infants and young children, baby foods, processed cereal based foods for infants and young children. The outcome of the stakeholder consultation shall be discussed in detail at the next working group meeting.

- sampling and analytical requirements for the official control of pyrrolizidine alkaloids, ergot alkaloids, tropane alkaloids, glycidyl fatty acid esters, 3-MCPD fatty acid esters, perchlorate and acrylamide

The Committee was informed on the provisions currently under discussion.

- other issues

The Committee received a short update on the ongoing discussion regarding T-2 and HT-2 toxins, DON and modified forms, *Alternaria* toxins, Acrylamide (other than the maximum levels under discussion), furan, "recast" of Regulation (EC) 1881/2006 and opium alkaloids. A delegation indication that a maximum level for morphine (and codeine) in poppy seeds would be needed.

As regards the almonds from US, the Committee reminded that it was agreed at the meeting on 17 April 2018, following some RASFF notifications as regards the presence of aflatoxins in almonds from US, that it was appropriate to be vigilant and that therefore the sampling frequency of < 1 % provided for in Regulation (EU) 2015/949 is temporarily not applicable. Following the improvement of the situation since 1 October 2018 as regards compliance, consideration was given to the return to the sampling frequency as provided by Regulation (EU) 2015/949. However, given 3 recent RASFF notifications, it was found premature to already return to it.

Finally, the Committee was reminded of the issue raised at the meeting in September of the situation that an own control by a potential buyer of a lot already on EU territory (in transit) has demonstrated that the concerned lot was not compliant with EU legislation as regards aflatoxins. The question was put forward as regards the obligation of the food business operator to inform thereof the competent authority, given the risk these lots are traded further with the possibility that these lots could, at a later stage, be placed on the EU market.

The Commission committed at that meeting to request a formal legal opinion on this question. The Committee was informed that the issue will be discussed at the next meeting of the Committee.

B.01 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 furan-2(5H)-one.

The Commission presented the text of the draft Regulation.

The European Food Safety Authority concluded, in its opinion published end of January 2019, that the flavouring substance furan-2(5H)-one (FL no. 10.066), under evaluation, raises a safety concern as it is genotoxic in vivo.

Its use as a flavouring substance therefore does not comply with the general conditions of use of flavourings set out in Regulation (EC) No 1331/2008.

The draft Regulation removes this flavouring substance from the Union list of flavourings and source materials. Its use in and on food is therefore no longer authorised, from the date of application of the draft Regulation. The Regulation follows the urgency procedure foreseen in Article 7(6) of the Regulation (EC) 1331/2008.

The UK formulated the following statement:

"*The UK supports urgent risk management action when a risk assessment, adhering to international guidelines, confirms a flavouring substance is genotoxic in vivo. For furan-2(5H)-one, EFSA has discounted one of the acceptability criteria required in the OECD test guideline and so the result may be described as equivocal and so requires further scientific consideration. Whilst we have concerns over the risk assessment, the UK can support the measure as this flavouring is no-longer used in foods and so there will be limited impact*."

Vote taken: Unanimity.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) authorising the placing on the market of the novel food biomass of yeast Yarrowia lipolytica 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 the novel food biomass of yeast Yarrowia lipolytica under Regulation (EU) 2015/2283 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) 2017/2470. The measure authorises the placing on the market of Yarrowia lipolytica yeast biomass as a novel food for use in food supplements, excluding food supplements for infants and young children.

The Netherlands made the following statement:

"*The EFSA assessment concludes that the proposed use of this specific Yarrowia lipolytica biomass product in food supplements is safe, and supports an authorisation decision. At the same time, however, we would like to point out that Yarrowia lipolytica may be used in future to develop a wide variety of "biomass"-products, containing components not covered in the current specification. Examples are ongoing applications for Cr-enriched and Se-enriched biomass products, and a rapidly evolving body of scientific literature highlights the potential to use this organism for the production of many other compounds of interest. We are concerned that the proposed generic authorisation for the biomass of this production organism may be regarded as a license to market any future Yarrowia lipolytica biomass product, that may include other compounds of interest, as long as these products meet the general specification. We have expressed this concern in the Novel Food Working Group (CAFAB) meeting on 12 March 2019, and by e-mail to the Commission,*

following that meeting. We would welcome a general discussion of this fundamental matter in a future CAFAB-meeting."

Vote taken: Unanimity.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Regulation correcting certain language versions of Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives.

The Commission presented a draft Commission Regulation correcting the CZ, LV and SK language versions of Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives. Errors were identified in Annex II, Part E (conditions of use of authorised food additives), which had to be corrected in order to ensure legal clarity for food business operators and the smooth functioning of the internal market. The errors concerned food categories 02.1, 02.2.2, 04.2.5.1, 04.2.5.2, 04.2.5.3, 08.2, 08.3.1, 08.3.2, 08.3.3, 14.1.4, 15.1 and 15.2. in the CZ language version, food category 04.1.2. in the LV language version and food category 07.1. in the SK language version. After discussion, it was agreeed to include in the text to be voted a linguistic amendment, as proposed by SK (the text 'čiastočne upečené balené pečivo určené na maloobchodný predaj' in the 5th column of the table in Article 1, Point 2g is replaced by the text 'předpečené balené pečivo určené na maloobchodný predaj').

Vote taken: Unanimity.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food.

The Committee was informed that this item had to be postponed as the internal administrative procedures could not be completed on time.

Vote Postponed

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Recommendation on a coordinated control plan with a view to establishing the prevalence of certain substances migrating from materials and articles intended to come into contact with food.

The Commission presented the draft Recommendation. In order to coordinate controls being carried out in Member States, a number of Food Contact Materials (FCMs) and substances have been discussed in the Expert Working Group on FCMs and compiled in the Recommendation. The sampling and analysis to be undertaken by Member States' Competent Authorities is foreseen from May – October 2019, with results to be reported by the end of the year. The Commission's Joint Research Centre as the EU-Reference Laboratory will support this work where necessary. Reporting may also include results from relevant controls carried out over the previous five years. The information generated will lead to a better understanding of the possible issues concerning migration of substances from FCMs imported into or on the EU market. The Commission confirmed that it would prepare a document for the parameters to be reported and discuss the format for reporting in the Working Group.

Vote taken: Favourable opinion.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation imposing special conditions governing the import of groundnuts from Gambia and Sudan and amending Regulations (EC) No 669/2009 and (EU) No 884/2014.

Commission Regulation (EC) No 669/2009 provides for an increased level of official controls on imports of certain feed and food of non-animal origin listed in Annex I to that Regulation. The results of the official controls carried out by the Member States pursuant to Regulation (EC) No 669/2009 on groundnuts from Gambia and Sudan show a continuous high frequency of non-compliance with maximum levels of aflatoxins. In order to protect human and animal health in the Union, it is necessary to provide for additional guarantees in relation to those food and feed.

Given the high level of non-compliance and the outcome of the Commission's audit in November 2018, it is foreseen to increase the frequency of identity and physical checks of aflatoxin in dried figs from Turkey from 10 to 20 %. The situation shall be reviewed at the next review of Regulation 884/2014 in the frame of the intended merge with Regulation (EC) 669/2009 in application of the Official Control Regulation (EU) 2017/625

Furthermore, it is foreseen to exclude from the scope trade samples or display items for exhibitions, which are not intended to be placed on the market or are sent to be used for scientific purposes.

In addition, there has been some changes in competent authorities whose authorised representative is entitled to sign the health certificate and some CN codes are updated.

Vote taken: Unanimity.

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending and correcting Regulation (EC) 1881/2006 as regards maximum levels of erucic acid and hydrocyanic acid in certain foods.

On 21 September 2016, the Scientific Panel on Contaminants in the Food Chain (CONTAM) of the European Food Safety Authority (EFSA) adopted a scientific opinion on erucic acid in feed and food. Data on the presence of erucic acid in vegetable oils and fats indicate that for most vegetable oils and fats, lower levels can be achieved by applying good practices. Therefore, it is appropriate to lower the maximum level for vegetable oils with the exception of camelina oil, borage oil. For camelina and borage oil, evidence has been provided demonstrating that it is not possible to achieve lower levels by applying good practices.

Given that a maximum level for erucic acid has already been established in infant formulae and follow-on formulae by Commission Delegated Regulation (EU) 2016/127, it is not necessary to establish a maximum level for erucic acid in infant formulae and follow-on formulae by Regulation (EC) 1881/2006.

Given that the unit in which the maximum level for hydrocyanic acid is not mentioned in the published version of Commission Regulation (EU) 2017/1237, it is foreseen to correct this in order to provide legal certainty.

Mustard oil contains naturally high levels of erucic acid but is in Europe only used in very small quantities in the preparation of certain foods.

A delegation re-iterated that it does not agree that no maximum level for erucic acid would be established in infant formulae and follow-on formulae in the frame of this Regulation.

Given that the issue of the presence of erucic acid in mustard oil and the use of mustard oil as food requires a more detailed discussion at working group level, it was decided to postpone the vote on this measure to the next meeting of the Committtee.

Vote Postponed

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) amending Regulation (EC) No 1881/2006 as regards maximum levels of citrinin in food supplements based on rice fermented with red yeast *Monascus purpureus.*

A maximum level of citrinin in food supplements based on rice fermented with red yeast *Monascus purpureus* is set by Regulation (EC) 1881/2006**.** Given the gaps in knowledge as regards the presence of citrinin in red yeast rice preparations and other foodstuffs and the remaining uncertainties as regards the carcinogenicity and genotoxicity of citrinin, it was foreseen to review the maximum level once more information has been gathered as regards the toxicity of citrinin and the exposure from other foodstuffs.

Following a call from EFSA to investigate the concentrations of citrinin in food samples with special focus on grains and grain-based products and red yeast rice preparations from different geographic regions in Europe, a report was published in 2017.

These new occurrence data indicate that there is no need to regulate for the time being citrinin in food other than red yeast rice supplements. Furthermore, it is evident that, by applying good manufacturing practices, the level of citrinin in food supplements based on rice fermented with red yeast *Monascus purpureus* is much lower than the current maximum level.

It is therefore foreseen by this draft Regulation to lower the maximum level for citrinin in these food supplements from 2000 µg/kg to 100 µg/kg. No new information on the toxicity has become available.

Vote taken: Unanimity.

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Regulation on reference points for action for non-allowed pharmacologically active substances present in food of animal origin and repealing Decision 2005/34/EC.

The Commission presented the proposal and the outcome of the public feedback. Comments were received from the European Livestock and Meat Trades Union, indicating that it has no problem with the current draft.

Furthermore an anonymous comment was received, indicating that according to Decision 2002/657/EC the CC alpha value of the method should be much lower than the RPA and that therefore the proposed Reference Points for Action (RPAs) are not analytically achievable. The Commission explained that, according to Decision 2002/657/EC, the RPA is calculated for forbidden substances at the limit of detection, to which a factor is added for covering the measurement uncertainty. The currently

proposed RPAs are based on the CC alpha values, which were reported as feasible by the national reference laboratories.

The anonymous commenter also requested to ensure that the RPAs would also apply to non-edible matrices. The Commission explained that this is today not the case and that it is also not needed, as RPAs are set to avoid trade disruptions for food. For non-edible matrices like urine or blood, Member States can enforce the lowest residues concentrations which can be reliably identified.

2 Member States commented that they consider the existing RPAs as being sufficient to ensure food safety and that lower RPAs, bringing along higher analysis cost, would not be appropriate. The Commission explained that EFSA was not able to conclude on the carcinogenicity of one of the nitrofuran metabolites and of chloramphenicol and that ,therefore, the RPAs for these substances should be set at a level as low as analytically achievable. Two Member States expressed their support to the proposal, pointing to fact that it concerns prohibited substances and that it is important to enforce as low concentrations as analytically achievable.

One Member State voted against, because it fears that it will not be able to enforce the lowered RPAs because of analytical problems. One Member abstained for analytical reasons and indicated that it would prefer maintaining the existing RPA for the nitrofuran metabolites, instead of lowering it. One Member State abstained because it was not yet able to take a position on the proposal.

Vote taken: Favourable opinion.

M.01 Any Other Business.

A delegation raised the issue that, in 2006, a declaration was endorsed at the Standing Committee for the presence of the unauthorised colour Sudan 4 in food. An action level was set at 500 ppb. However, it was noticed that recently RASFF notifications were issued for the unauthorised presence of Sudan dyes at levels much lower than 500 ppb. The delegation questioned if the declaration of 2006 was still valid.

The Commission's representative clarified that, in 2006, the method of analysis used for the detection of the unauthorised use of Sudan dyes was HPLC. The level of 500 ppb was in 2006 the limit of quantification which was achievable by routine control laboratories. However more recently LC-MS/MS is applied to detect the unauthorised presence of Sudan dyes in food. Levels of quantification as low as 10 µg/kg can be achieved. Given that the use of Sudan dyes in food is prohibited, every confirmed/quantified finding is a non-compliance, and can consequently result in a RASFF notification. It was acknowledged that it would be appropriate to update the declaration of 2006 taking into account the technical progress and the sensitivity of the currently used methods of analysis. One delegation, although acknowledging the need to update the 2006 declaration, indicated that, in view of lowering the action level, not only the sensitivity of the method should be taken into account, but also the unavoidable cross-contamination.