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Standing Committee on Plants, Animals, Food and Feed
Section *Novel Food and Toxicological Safety of the Food Chain*
18 November 2019

CIRCABC Link: *https://circabc.europa.eu/w/browse/dadce298-c995-4bc1-a587-a169639d1edb*

SUMMARY REPORT

A.01 Presence of mineral oil hydrocarbons (MOH) in food and food contact materials.

a) Presence of mineral oil aromatic hydrocarbons (MOAH) in infant formula and follow-on formula.

- **Presentation of the EFSA rapid risk assessment**
- **Discussion on analytical aspects**
- **Discussion on harmonised risk management measures**

Following the findings by Foodwatch of the presence of mineral oil aromatic hydrocarbons (MOAH) in infant formula and follow-on formula and the request from a Member State to have a harmonised EU risk management approach in relation to these findings, the Commission services requested the relevant competent authorities to sample the batches of infant formula which have been found to contain MOAH and to perform investigations on the source of contamination, and to report the outcome of these controls and investigations to the Commission and to EFSA.

The European Commission has asked EFSA to carry out a rapid risk assessment on the risks for public health related to the presence of mineral oil aromatic hydrocarbons (MOAH) in infant formula and follow-on formula, taking into account the analytical results received.

At the meeting of the Standing Committee, the outcome of the Rapid Risk Assessment was presented by EFSA and its follow-up extensively discussed.

EFSA concluded that, in the absence of information on the presence or absence of 3-7 ring polycyclic aromatic compounds (3-7 PAC), the detection of MOAH in food should be considered of potential concern for human health.

EFSA recommended that analytical methods to identify 3-7 PAC should be routinely applied when MOAH are detected in food. The evaluation of the analysis chromatograms related to the monitoring of MOH in food is important for risk assessment purposes. Such chromatograms should therefore be made available upon request of risk assessors.

The Committee acknowledged that even when the Joint Research Centre (JRC) "Guidance on sampling, analysis and data reporting for the monitoring of mineral oil hydrocarbons in food and food contact materials" is applied, as the JRC Guideline is not a Standard Operating Procedure for MOAH analysis in a particular matrix (type of food), only analytical results obtained by applying equivalent analytical procedures for the whole analytical process (including sample preparation) can be compared.

Therefore, the Committee was informed that the JRC will organise, on request of and in co-operation with DG Health and Food Safety, on 5 December 2019 a workshop on the determination of MOAH in infant formula, at which all interested parties shall be invited to participate. The workshop is organised to ensure a further harmonisation of the procedure for the determination of MOAH in infant formula (identification and quantification of MOAH in such samples, including sample preparation, all other analytical steps and signal/data treatment) which should result in obtaining comparable results and address the uncertainties as regards the characterisation of the MOAH fraction, as highlighted in the EFSA Rapid Risk Assessment.

It is appropriate and important that (official and commercial) laboratories apply the JRC guidance on sampling, analysis and data reporting, as well as and the conclusions to come of the abovementioned workshop on 5 December 2019, when analysing MOAH in infant formula and follow-on formula (and in food in general).

The Committee agreed on the following conclusions:

- Member States, food business operators, consumer organisations, NGOs and other interested parties are requested to continue to provide to EFSA occurrence data on the presence of MOAH in infant formula, sampled, analysed and reported in accordance with the abovementioned JRC guidance on sampling, analysis and data reporting and the conclusions of the workshop on 5 December 2019.
- As soon as sufficient occurrence data on the presence MOAH in infant formula are provided to EFSA, in accordance with the JRC guidance on sampling and analysis and the conclusions of the workshop on 5 December 2019, EFSA shall be requested to update without delay the Rapid Risk Assessment on the possible risk for public health due to the contamination of infant formula and follow-on formula by mineral oil aromatic hydrocarbons (MOAH).
- Appropriate harmonised risk management measures as regards the presence of MOAH in infant formula and follow-on formula shall be discussed and agreed in the Standing Committee upon availability of EFSA's updated Rapid Risk Assessment.
- Given the current uncertainties related to the analysis of MOAH in infant formula and consequently the uncertainties as regards the potential risk for public health, the Committee agreed that, following the above-mentioned findings of MOAH, and for the time being, no action is to be taken as regards the withdrawal or recall of infant formula and follow-on formula present on the market, until harmonised risk management measures are agreed after EFSA's updated Rapid Risk Assessment becomes available.

b) Monitoring results of mineral oil hydrocarbons (MOH) in food and food contact materials as a result of Commission Recommendation (EU) 2017/84 on the on the monitoring of mineral oil hydrocarbons in food and in materials and articles intended to come into contact with food

- **Exchange of views on the available monitoring results**
- **Discussion on further (regulatory) follow-up.**

EFSA presented a preliminary overview of the occurrence data currently available at EFSA on Mineral Oil Hydrocarbons (MOH). It was concluded that there were several food groups for which only a limited amount of data were available, but which nevertheless indicated a significant presence of MOSH and MOAH. It was therefore agreed to continue the monitoring for another year, stressing the importance that the JRC "Guidance on sampling, analysis and data reporting for the monitoring of mineral oil hydrocarbons in food and food contact materials" is applied as well, if appropriate, possible conclusions of the workshop to be held on 5 December 2019.

The foods/food groups to which special attention should be paid in the coming year for monitoring will be determined in the upcoming meeting of the Working group on Industrial and Environmental contaminants on 9 December 2019. This should be foods /food groups for which only a limited amount of data is available, but which nevertheless indicate a significant presence of MOSH and MOAH. This can be foods/food groups already specifically mentioned in the Commission Recommendation (EU) 2017/84 of 16 January 2017 on the monitoring of mineral oil hydrocarbons in food and in materials and articles intended to come into contact with food but also, food /food groups which are not.

A.02 Exchange of views on the conditions governing the import of food, minor food and feed originating in third countries following the accident at the Chernobyl nuclear power station.

Council Regulation (EC) No 733/2008 lays down maximum permitted levels of radioactivity in certain agricultural products originating in third countries. It also establishes that Member States are required to carry out checks on such products, in order to ensure their compliance with the levels of radioactivity set out in that Regulation, before the product is released for free circulation. It shall expire on 31 March 2020, unless decided otherwise at an earlier date.

An exchange of views took place on the measures that should remain applicable after 31 March 2020 as regards the import of food and feed originating in third countries affected by the accident at the Chernobyl nuclear power station, in particular on the following aspects

- maximum levels of radioactive caesium
- for which feed and food official certificates would be required
- official controls at border control posts
- costs and release for circulation
- review clause

Several Member States stressed that the measures should not be more restrictive than what is currently applicable in several Member States.

The Commission representative informed that a draft text is being prepared, for discussion and possible opinion at the next meeting of the Committee.

A.03 Exchange of views of the alignment of control provisions of Commission Implementing Regulation (EU) 2016/6 to the Official Control Regulation (EU) 2017/625.

The Commission presented the list of amendments that are needed to align the control provisions of Commission Implementing Regulation (EU) 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 to the Official Control Regulation (EU) 2017/625.

No comments were made and the Commission representative informed that a draft is being prepared for discussion and possible opinion at the next meeting of the Committee.

The Commission furthermore informed the Committee that, in Annex III of the Commission Implementing Regulation (EU) 2019/1787 of 24 October 2019 amending Implementing Regulation (EU) 2016/6, "the declaration for the import into the Union" at the third bullet point of the declaration the words "or processing" are missing after "transiting" (as currently provided for in Regulation 2016/6). This will be corrected by the aforementioned draft to be developed. The Committee was also informed that the Japanese authorities told the Commission of their intention to already add the words "or processing" to the declarations which will accompany the consignments. No objections were raised and the Commission representative indicated that the Japanese authorities will be informed thereof.

A.04 Exchange of views on topics discussed in recent meetings of the Working Groups on agricultural contaminants.

The Committee was informed on the status of the different files currently under discussion in relation to agricultural contaminants in food:

- Technical discussions finalised /close to finalisation: Maximum levels for pyrrolizidine alkaloids, for ergot sclerotia and ergot alkaloids and for tropane alkaloids
- Targeted stakeholder consultation to be launched for maximum levels for opium alkaloids
- Methods of sampling and performance criteria for methods of analysis for ergot sclerotia and ergot alkaloids and for plant toxins (pyrrolizidine alkaloids, tropane alkaloids and hydrocyanic acid) have been developed and will be included in a draft legal text.
- Discussions ongoing on the follow-up to be given to recent EFSA opinions on quinolizidine alkaloids and on hydrocyanic acid.

Initial discussions ongoing regarding the maximum levels for T-2 and HT-2 toxin and for deoxynivalenol (3-Acetyldeoxynivalenol, 15-acetyldeoxynivalenol and Don 3-glucoside)

A.05 Presentation of Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC.

The changes as introduced by Regulation (EU) 2019/1381, which will enter into application on 27 March 2021 were presented in detail. The preparatory work which has to be carried out both by EFSA and by the Commission in close co-operation before the entry into application was explained. In particular the need to align existing guidance/implementing acts in sectorial legislation to the new rules, to adopt by implementing act the general plan on risk communication and to adopt by implementing act standard data formats for applications was highlighted.

An exchange of views took place as regards the approach and timing for the development of the implementing act on risk communication. Furthermore, it was stressed that, besides providing sufficient resources to EFSA to fulfil the required tasks in relation to transparency and risk assessment, it is equally important to provide sufficient resources for the risk management.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation authorising the change of the specifications of the novel food coriander seed oil from *Coriandrum sativum* 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 authorising authorising the change of the specifications of the novel food coriander seed oil from *Coriandrum sativum* 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 change in the level of oleic acid naturally present in the oil from the coriander (*Coriandrum sativum)* seeds from the currently authorised level of 8% to the proposed 7% to account for the natural variation in the levels of oleic acid in the plant seeds.

The Committee delivered its opinion with no objections.

Vote taken: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation authorising an extension of use of chia seeds (*Salvia hispanica*) as a novel food and the change of the conditions of use and the specific labelling requirements of chia seeds (*Salvia hispanica*) 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 authorising an extension of use of chia seeds (Salvia hispanica) as a novel food and the change of the conditions of use and the specific labelling requirements of chia seeds (*Salvia hispanica*) under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470. The measure authorises an extension of use of chia seeds (Salvia hispanica) as a novel food in a number of foods which do not require heat treatment at

or above 120 °C in their manufacture, processing or preparation. Furthermore, as EFSA confirms that chia seeds (Salvia hispanica) are safe without any specific restrictions and precautions regarding their use levels, this measure also removes the maximum levels of already authorised food categories, listed in the Union list of authorised novel foods, which do not require heat treatment at or above 120 °C in their manufacture, processing or preparation, as well as the specific labelling requirement relating to the maximum daily intake.

The Committee delivered its opinion with no objections.

Vote taken: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation authorising the placing on the market of nicotinamide riboside chloride as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470.

The Commission presented the draft Commission Implementing Regulation authorising the placing on the market of nicotinamide riboside chloride as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470. The measure authorises the placing on the market of nicotinamide riboside chloride as a novel food. The novel food is intended to be used as a source of niacin in food supplements for the general adult population. This measure also concerns authorising the data protection in accordance with Article 26 of Regulation (EU) 2015/2283.

The Committee delivered its opinion with no objections.

Vote taken: Favourable opinion.