



EUROPEAN COMMISSION

Health and Food Safety Directorate General

sante.ddg2.g.5(2020)4661897

Standing Committee on Plants, Animals, Food and Feed
Section Novel Food and Toxicological Safety of the Food Chain
23 June 2020

CIRCABC Link: <https://circabc.europa.eu/w/browse/63516748-c0a6-4b97-b8cc-7eb662477c29>

SUMMARY REPORT

A.01 Presence of mineral oil aromatic hydrocarbons (MOAH) in infant formula and follow-on formula – conclusion on harmonised risk management measures.

Reference was made to the previous discussions on the findings of presence of mineral oil aromatic hydrocarbons (MOAH) in infant formula and follow-on formula, especially at the last meeting of the Committee in February 2020 in which the Member States agreed that an EU harmonised risk management approach would be appropriate to ensure a high level of human health protection. More details and background had been requested on the proposed risk management approach in order to be able to take a final common position. After the Commission representative provided these details and background, despite a common willingness by a majority of the delegations to agree on an approach, no common agreement could be found via the following electronic consultation. Therefore, the discussion on a common risk management approach continued at this meeting.

The Committee was reminded that in case the [Joint Research Centre \(JRC\) guidance](#) and the [conclusions of the workshop of 5 December 2019](#) are complied with, quantified levels of total MOAH above 2 mg/kg strongly indicate a presence of MOAH. For a more precise determination of the Limit of Quantification (LOQ), a Standard Operating Procedure (SOP), specific for the matrix, as well as reference materials, have to be developed. For a quantification of 3-7 PAC, more work has to be performed on the development of the method of analysis. Due to the COVID-19 crisis, the work on the SOP and the more precise determination of the LOQ undertaken by the JRC have been delayed.

The JRC confirmed that, as an alternative to the 2 mg/kg as LOQ for total MOAH, an LOQ of 1 mg/kg per MOAH C-fraction¹ could be considered. This alternative is stricter than the criterion of LOQ of 2 mg for total MOAH as, for any finding of more than 2 mg/kg total MOAH, there was always at least one MOAH fraction above 1 mg/kg.

After some discussion, the Committee agreed to the following statement:

¹ [It concerns the following MOAH C-fractions: MOAH > n-C10 to < n-C16, MOAH > n-C16 to < n-C25, MOAH > n-C25 to < n-C35, MOAH > n-C35 to < n-C50.](#)

“Presence of Mineral oil aromatic hydrocarbons (MOAH) in infant formula, follow-on formula, foods for special medical purposes intended for infant and young children and young child formula

The European Food Safety Authority (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 mineral oil aromatic hydrocarbons (MOAH) in food should be considered of potential concern for human health². Therefore, MOAH should not be present in infant formula and follow-on formula. The presence of MOAH has been confirmed in infant formula and follow-on formula.

Good practices exist to prevent the presence of MOAH in infant formula, follow-on formula, foods for special medical purposes intended for infants and young children and young child formula. There is evidence that, through a careful selection of batches of vegetable oils to be used for the production of infant formula and follow-on formula, the presence of MOAH in these foods can be significantly reduced or even prevented. Contaminant levels shall be kept as low as can reasonably be achieved by following good practices at all the stages (Article 2(2) of Regulation (EEC) 315/93). Therefore, food business operators along the production chain shall apply these good practices to prevent presence of MOAH in these foods.

The Committee concluded that batches of infant formula, follow-on formula, foods for special medical purposes intended for infants and young children and young child formula containing an analysed content (*i.e. no measurement uncertainty to be taken into account*) of 1 mg/kg MOAH per MOAH C-fraction³ (*sample preparation and analysis in accordance with the [JRC guidance](#) and the [conclusions of the workshop of 5 December 2019](#)*) provide clear evidence of presence of MOAH in these products and are therefore of concern for public health. Measures as regards such batches should be taken to ensure a high level of human health protection and this in accordance with [Article 14 of Regulation \(EC\) 178/2002](#).

The level 1 mg/kg MOAH per MOAH C-fraction is currently the lowest level that can be reliably quantified in laboratories across the EU and is temporary awaiting the finalisation of the specific Standard Operating Procedure for the analysis of MOAH in infant formula, follow-on formula, foods for special medical purposes intended for infants and young children and young child formula which shall enable a better estimation of the achievable LOQ in these matrices.”

Statement from the delegation of Germany in relation to this conclusion

„For Germany, protection of the health of consumers, especially of infants and young children, is very important and a common approach as regards mineral oil hydrocarbon contamination in infant formula and follow-on formula is strongly supported. However, Germany would like to express concerns regarding a limit of quantification (LOQ) for MOAH of 1 mg/kg per fraction having in mind that in Germany official laboratories in general reliably achieve a LOQ of at least 0,5 mg/kg per fraction.

² [EFSA \(European Food Safety Authority\), Arcella D, Baert K, Binaglia M, 2019. 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 \(MOAH\). EFSA Supporting Publication 2019: EN-1741. 18pp. doi:10.2903/sp.efsa.2019.EN-1741](#)

³ It concerns the following MOAH C-fractions: MOAH \geq n-C10 to \leq n-C16, MOAH $>$ n-C16 to \leq n-C25, MOAH $>$ n-C25 to \leq n-C35, MOAH $>$ n-C35 to \leq n-C50.

Germany noted that the EU-limit is proposed on a temporary basis and we urge the Commission to lower the proposed limit as fast as can be to ensure a best possible level of consumer protection throughout the EU.“

The Commission representative stressed again, based on the advice from the Joint Research Centre, that the LOQ of 1 mg/kg per MOAH fraction is for the time being the lowest level that can be put forward as LOQ in an EU harmonised risk management approach, while acknowledging that it is not excluded that certain laboratories can already perform better.

Taking into account the levels of MOAH reported by EFSA in processed cereal based foods for infant and young children, the Committee is of the opinion that it is appropriate to examine without delay these analytical results in detail and to determine, if appropriate, also for these foods, an EU harmonised risk management measure to ensure a high level of human health protection for this vulnerable group of the population.

A.02 Endorsement of the follow-up to be given to the EFSA opinion on quinolizidine alkaloids.

EFSA adopted on 25 September 2019 a [scientific opinion on the risks for animal and human health related to the presence of quinolizidine alkaloids in feed and food, in particular in lupins and lupin-derived products](#).

Due to the limited data on occurrence and consumption, dietary exposure was calculated for some specific scenarios and no full human health risk characterisation was possible. The calculated margin of exposures (MOEs) may indicate a risk for some consumers.

The EU Reference Laboratories (EURL) confirmed that there is no validated analytical method with sufficient sensitivity for the analysis of the most relevant quinolizidine alkaloids (i.e. lupanine, 13-hydroxylupanine, angustifoline, multiflorine, isolupanine, albine, 13-tigloyloxylupanine, sparteine, lupinine) in lupins and lupin derived foods.

Therefore, the Committee agreed that:

- it is appropriate that the EURL, in co-operation with the National Reference Laboratories (NRLs), undertakes work on a method of analysis with sufficient sensitivity for the analysis of the most relevant quinolizidine alkaloids in the year 2021. The EURL is requested to report the outcome of this work by the end of 2021.
- on the basis of the information provided by the EURL and the outcome of EFSA's risk assessment, appropriate risk management measures will then be discussed (including the possibility of gathering additional occurrence data).

A.03 Exchange of views on draft Regulations related to the setting of maximum levels of

- ergot sclerotia and ergot alkaloids**
- tropane alkaloids**
- opium alkaloids**

The Committee was informed on the status of these draft Regulations.

As regards the provisions on maximum levels of ergot sclerotia and ergot alkaloids, it is foreseen that the maximum levels would apply as from 1 July 2021 (*start of the new cereal harvest season*) and to consider a consequent delay of the possible application of lower levels for ergot sclerotia/ergot alkaloids in rye and rye milling products and in milling products of barley, wheat, spelt and oat grains, following an assessment of the achievability of the stricter levels in the different producing regions in the EU. In addition, the exemption for wheat intended to be processed by wet milling of the maximum level for ergot sclerotia is deleted, following information of possible increased levels of ergot alkaloids in co-products intended for human consumption.

The foreseen date of entry into application of the possible maximum levels for tropane alkaloids would be 1 September 2022.

For opium alkaloids, the date of the entry into force for the possible maximum levels in whole, ground, milled poppy seeds placed on the market for the final consumer and bakery products containing poppy seeds and/or derived products derived thereof is to be determined at the moment the draft Regulation is submitted for opinion.

A.04 Exchange of views on draft implementing Regulations related to the establishment of sampling procedures and performance criteria for methods of analysis

- ergot sclerotia and ergot alkaloids
- plant toxins: pyrrolizidine alkaloids, tropane alkaloids, opium alkaloids

The Committee was informed on the envisaged provisions on sampling and analysis. Its attention was drawn to the envisaged procedure for the visual/microscopic examination of the samples for the presence of ergot sclerotia.

For plant toxins, it is foreseen to develop a specific Commission Implementing Regulation on the sampling and analysis of plant toxins (*pyrrolizidine alkaloids, tropane alkaloids, opium alkaloids, hydrocyanic acid and erucic acid*) in food, thereby integrating and replacing the provisions in Commission Regulation (EU) 2015/705 of 30 April 2015 laying down methods of sampling and performance criteria for the methods of analysis for the official control of the levels of erucic acid in foodstuffs and repealing Commission Directive 80/891/EEC

A.05 Exchange of views on topics discussed in recent meetings of the Working groups on contaminants, in view of a targeted stakeholder consultation

- hydrocyanic acid
- tetrahydrocannabinol (THC)
- T-2 and HT-2 toxin
- DON and modified forms

The following draft measures are foreseen for targeted stakeholder consultation:

Maximum levels of hydrocyanic acid in

- unprocessed whole, ground, milled, cracked chopped linseed
- unprocessed whole, ground, milled, cracked chopped almonds placed on the market for the final consumer
- cassava (fresh, peeled)
- cassava flour

Maximum levels of tetrahydrocannabinol (THC) (maximum levels refer to the sum of Δ^9 -THC and Δ^9 -THCA)

- hemp seeds
- ground hemp seeds (hemp seed powder), (partially) defatted hemp seed (press cake) (hemp seed flour), hemp seed bran
- hemp seed oil:

Maximum levels of T-2 and HT-2 toxin in unprocessed cereals, cereal grains placed on the market for the final consumer, cereal products (including cereal milling products, bread, pastries, biscuits, cereal snacks, breakfast cereals, pasta and cereal based foods for infants and young children)

Revised maximum levels of deoxynivalenol (DON) in unprocessed cereals, cereal grains placed on the market for the final consumer, cereal products (including cereal milling products, bread, pastries, biscuits, cereal snacks, breakfast cereals, pasta and cereal based foods for infants and young children)

It was pointed out that maximum levels are proposed for the parent compound only given that it is considered premature to establish maximum levels based on the sum of the DON and modified forms. However in accordance with the outcome of the EFSA opinion, it is important to continue gathering information on the presence of modified forms, in view of a possible future setting of maximum levels for the sum of DON and modified forms.

As regards the year-to-year variation of prevalence and level of contamination of cereals by mycotoxins, in particular *Fusarium* toxins, concerns were raised that in some years a substantial part of the EU cereal production could be affected by extreme climate conditions, resulting in higher levels of contamination by *Fusarium* toxins. This could potentially endanger the supply of cereals and cereal products, complying with the proposed strict levels. The Commission representative acknowledged that this is an issue, which needs to be addressed.

A.06 Feedback and exchange of views on topics discussed in recent meetings of the Working groups on contaminants

- ochratoxin A
- aflatoxins

Taking into account the recent EFSA scientific opinions on public health risks related to the presence of [ochratoxin A \(OTA\)](#) and [aflatoxins](#) in food, discussions are ongoing in the working group to update the already comprehensive EU legislation to continue to ensure a high level of public health protection.

The Committee was informed on the discussions on the setting of maximum levels of ochratoxin A in food commodities for which currently no maximum level has been established at EU level (*such as certain dried fruits, dried herbs, tea and herbal infusions, certain oilseeds, certain tree nuts, cocoa powder*) and the possible lowering of maximum levels for certain cereal products.

As regards aflatoxins, discussions are still at a very premature phase.

A.07 Exchange of views on the alignment to the Official Control Regulation (Regulation EU) 2017/625) of the control provisions provided in 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.

The Committee was informed of the envisaged changes aimed at aligning the control provisions in Implementing Regulation (EU) 2016/6 to the Official Control Regulation (EU) 2017/625. The envisaged changes are similar to the control provisions as provided in the draft Commission Implementing Regulation (EU) on the conditions governing imports of food and feed originating in third countries following the accident at the Chernobyl nuclear power station (see point B.03).

No comments were made as regards these envisaged changes.

A.08 Bamboo as food contact material (endorsement of a common position).

The Commission presented a document reflecting the views of the Experts of the Working Group on Food Contact Materials, with a view to inform the Standing Committee on the latest position of the Working Group experts, with no intention to ask for a formal endorsement.

The document establishes that bamboo flour cannot be legally used in a plastic material if intended to be used in contact with food, as Bamboo flour is not listed as an additive in Annex I to Regulation (EU) No 10/2011.

While welcoming the document and the position therein, several Member States observed that it does not fully clarify how to address enforcement in practice, in particular as a potential temporary derogation could be considered, provided an application for the authorisation would be received. The Commission explained that the document establishes the common interpretation of the experts that form the PAFF Working Group on Food Contact Materials. The Commission cannot however provide a legal text that would establish such a derogation. Therefore, if the market situation in several Member States would justify introducing such a derogation, that should be established in a next amendment to Regulation (EU) No 10/2011.

A.09 Presentation of the F2F strategy for fair, healthy and environmentally-friendly food system.

The Commission presented to the Member States the recently adopted Farm to Fork (F2F) Strategy.

Following elements were highlighted in the presentation:

- the F2F strategy is part of the European Green Deal and aims at a fair, healthy and environmentally-friendly sustainable food system
- the 2030 targets as regards use and risk of chemical pesticides, reduction of nutrient losses, reduced sales of antimicrobials and increase of organic farming and organic aquaculture
- the need for an integrated approach from Farm to Fork
- a legislative framework for sustainable food systems

- actions to stimulate sustainable practices for the various actors in the food system with more details provided on the sustainable practices by food industry and retail, hospitality and food service. In that context the proposed revision of the EU legislation on Food Contact materials was explicitly mentioned.
- actions to promote a shift towards healthy, sustainable diets
- actions to reduce food loss and waste
- research and innovation
- promoting global transition

B.01 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 colours in salmon substitutes.

The Commission received an application for the authorisation of the use of Sunset Yellow FCF/Orange Yellow S (E 110) and Ponceau 4R, Cochineal Red A (E 124) in salmon substitutes based on the fish species *Clupea harengus*. Since there is a technological need for these colours and there is no exposure concern from the proposed extension of use, it is appropriate to grant these authorisations. In order to provide clarity and legal certainty as regards the term “salmon substitute” it is also appropriate to list the fish species considered as salmon substitutes (i.e. *Theragra chalcogramma*, *Pollachius virens* and *Clupea harengus*) also for the other provisions authorising the use of colours in such products.

The draft Regulation presented by the Commission to the Committee by written procedure concerned therefore the amendment of Annex II to Regulation (EC) No 1333/2008 as a follow-up to an application.

The Commission announced that it would launch the vote by written procedure in accordance with Article 3(5) of Regulation (EC) No 182/2011 shortly after the meeting of the Committee.

Vote taken by written procedure: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation authorising the placing on the market of vitamin D2 mushroom powder 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 vitamin D2 mushroom powder as a novel food. The novel food is intended to be used in a number of foods and in food supplements. The authorisation is underpinned by a positive EFSA opinion.

The Commission announced that it would launch the vote by written procedure in accordance with Article 3(5) of Regulation (EC) No 182/2011 shortly after the meeting of the Committee.

One Member State abstained and one Member State (The Netherlands) voted against and provided the following statement in support to its vote:

‘The authorization of vitamin D2 mushroom powder as a novel food is clearly to be used for vitamin D fortification purposes so we consider this novel food to be a new source of ergocalciferol. In the EU, we all aim at safe intake of vitamin D from various sources. Therefore specific European community legislation exists to control the combined intake of vitamins and minerals to ensure that the total daily exposure remains within safe levels. Besides this, many Member States have national provisions in place in anticipation of maximum levels to be set at European level. Although EFSA concluded that this vitamin D2 mushroom powder is safe under the conditions of use proposed by the applicant, we would like to note that EFSA’s estimates of combined intake of vitamin D from different sources (see Table 9 in the EFSA opinion) did not take into account the high-dose vitamin D food supplements that are nowadays authorized in many Member States (up to 100 µg/day). Also, the intake of vitamin D via previously authorized UV-treated novel foods was not considered by EFSA.

We therefore feel that it is not appropriate to specify individual food categories to which the NF may be added. Knowing that similar applications seeking authorization of vitamin D containing foods have been submitted already, the proposed authorization for the placing on the market of vitamin D2 mushroom powder as a novel food would set a precedent. That is why we still believe that replacing the two columns of the conditions of use in the Annex of the proposal with the statement “To be used in compliance with Directive 2002/46/EC, Regulation (EU) No 609/2013 and/or Regulation (EC) No 1925/2006”, would be the only adequate way to manage vitamin D intake via of all sorts of fortified foods in the diet using the therefore existing EU legislation framework. In this regard, we would like finally to refer to the letter sent recently to SANTE Commissioner Ms. Kyriakides with the joint position of 19 Member States (including The Netherlands) on setting maximum levels for vitamins and minerals in food supplements and fortified foods, calling upon the European Commission to resume this work on a timely manner’.

Vote taken by written procedure: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) on the conditions governing imports of food and feed originating in third countries following the accident at the Chernobyl nuclear power station.

The draft Regulation replaces Council Regulation (EC) No 733/2008 that expired on 31 March 2020. The draft Regulation provides for a maximum level of radioactive caesium to be applied to products imported from third countries affected by the Chernobyl nuclear power incident. Specific import conditions are established for wild mushrooms and wild forest berries for which non-compliance have been found in recent years.

As a result of the discussions, the following changes were agreed:

- the maximum level for radioactive caesium only relates to 137-caesium, as 134-caesium is in the meantime already completely decayed
- the frequency of control at import was established at 20 %

- minor amendments were introduced to the control provisions to ensure full alignment with provisions of [Commission Implementing Regulation \(EU\) 2019/1793](#)
- reference to the need to update [Commission Recommendation 2003/274/Euratom](#)

The Commission announced that it would launch the vote by written procedure in accordance with Article 3(5) of Regulation (EC) No 182/2011 shortly after the meeting of the Committee.

One Member State voted against as it did not agree with the frequency of 20 % of controls at import and was of the opinion that the initially proposed frequency of 50 % would be more appropriate for the protection of public health.

Vote taken by written procedure: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Regulation (EC) 1881/2006 as regards maximum levels of acrylamide in certain foodstuffs for infants and young children.

The draft Regulation establishes maximum levels for acrylamide in baby foods, biscuits, rusks and other processed cereal based foods for infants and young children, complementary to the measures provided in Commission Regulation (EU) 2158/2017 establishing mitigation measures and benchmark levels for the reduction of the presence of acrylamide in food.

The Commission announced that it would launch the vote by written procedure in accordance with Article 3(5) of Regulation (EC) No 182/2011 shortly after the meeting of the Committee.

Vote taken by written procedure: Favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Regulation (EC) 1881/2006 as regards maximum levels of pyrrolizidine alkaloids in certain foodstuffs.

The draft Regulation provides for the establishment of maximum levels for pyrrolizidine alkaloids in tea and herbal infusions, food supplements containing herbal ingredients, pollen and pollen products, dried herbs and cumin seeds. Pyrrolizidine alkaloids are genotoxic carcinogens and EFSA has concluded that the presence of pyrrolizidine alkaloids in these foods is of health concern.

In certain production regions, good agricultural and harvest practices have only been recently introduced or have still to be implemented. Therefore, it is appropriate to provide for a reasonable period to allow all production regions to introduce such practices. Two growing seasons are necessary for a full implementation of the good agricultural and harvest practices.

Taking into account that the foodstuffs covered by this Regulation have a long shelf life, it is appropriate to provide for a sufficiently long transitional period so that foodstuffs that have been lawfully placed on the market before the date of application of this Regulation can remain long enough on the market. A transitional period of 18 months is thus proposed to enable the selling to the final consumer of the products produced before the date of application.

After some discussion, the Committee agreed to the transitional period but one Member State, while not opposing to this transitional period, indicated that it is appropriate to elaborate a document setting out the criteria to be taken into account for setting a transitional period in order to ensure a consistent approach within the contaminants legislation.

The Commission announced that it would launch the vote by written procedure in accordance with Article 3(5) of Regulation (EC) No 182/2011 shortly after the meeting of the Committee.

Vote taken by written procedure: Favourable opinion.