

BACKGROUND INFORMATION TO THE STATEMENT

Mineral oil aromatic hydrocarbons 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 health¹. Therefore EFSA recommended that analytical methods to identify 3-7 PAC should be routinely applied when MOAH are detected in food. A workshop with all interested parties was organised on 5 December 2019 to discuss and conclude on harmonised sample preparation and analysis as a follow-up to this recommendation from EFSA². Competent authorities have been requested to monitor the presence of MOAH in infant formula and follow-on formula and to report these data to EFSA and the Commission. EFSA assesses these findings on the possible risk for public health in view of determining appropriate harmonised risk management measures.

The presence of MOAH was extensively discussed at the Standing Committee meetings on 18 November 2019³ and 21 February 2020⁴ in view to agree on appropriate harmonised risk management measures as regards the presence of MOAH in infant formula and follow-on formula, to ensure a high level of human health protection.

At the meeting of the Standing Committee on 21 February, EFSA presented their assessment of the data on the presence of MOAH received from Member States and came to the following conclusion

- presence of MOAH in infant formula has been confirmed with concentrations of MOAH in the range of 0.9 to 3.5 mg/kg
- considering the possible presence of 3-7 PAC in the MOAH, the estimated exposure for infants and toddlers is of concern for human health.

¹ 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

² Conclusions of the workshop are available at:

https://ec.europa.eu/food/sites/food/files/safety/docs/cs_contaminants_catalogue_outcome-workshop-moah_en.pdf

³ Summary report of the meeting of the Standing Committee on Plants, Animals, Food and Feed Section Novel Food and Toxicological Safety of the Food Chain on 18 November 2019

https://ec.europa.eu/food/sites/food/files/safety/docs/reg-com_toxic_20191118_sum.pdf

⁴ Summary report of the meeting of the Standing Committee on Plants, Animals, Food and Feed Section Novel Food and Toxicological Safety of the Food Chain on 21 February 2020

https://ec.europa.eu/food/sites/food/files/safety/docs/reg-com_toxic_20200221_sum.pdf

As regards hazard identification and characterisation, EFSA confirmed that there is no reference point for 3-7 PAC, that full toxicological characterisation of MOAH-containing substances is lacking. In addition, the risk characterisation of possible non-neoplastic hazards is not feasible if the presence of 3-7 PAC can be excluded.

The JRC confirmed at the meeting that in case the JRC guidance⁵ and the conclusions of the workshop on 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 LOQ, a Standard Operating Procedure (SOP), specific for the matrix, has to be developed (as well reference materials)

For a quantification of 3-7 PAC, more work has to be performed on the development of the method of analysis

It is of high importance that investigations as regards the source of the presence of MOAH in infant formula and follow-on formula are intensified and if identified, remediated.

Information available indicate that through a careful selection of vegetable oils to be used for the production of infant formula and follow-on formula, levels of MOAH in infant formula and follow-on formula can be reduced

Taking into account that

- EFSA confirms that the presence of MOAH in infant formula and follow-on formula is of concern for human health, and
- therefore, MOAH should not be present in infant formula and follow-on formula
- that the presence of MOAH has been confirmed in infant formula and follow-on formula at concentrations in the range of 0.9 to 3.5 mg/kg (lower bound)
- in the absence of a specific Standard Operating Procedure for the analysis of MOAH in infant formula and follow-on formula, there are still the analytical uncertainties in the analysis of MOAH in infant formula and follow-on formula in the lower range of quantified levels, and
- it is not yet possible to quantify reliably the presence of 3-7 PAC, and
- there are good practices 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 and that 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), and
- 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 infant formula and follow-on formula can be significantly reduced,

⁵ https://publications.jrc.ec.europa.eu/repository/bitstream/JRC115694/kjna29666enn_2.pdf

it can be 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-fraction⁶ (sample preparation and analysis in accordance with the JRC guidance and the conclusions of the workshop of 5 December 2019) provides clear evidence of presence of MOAH in these products and is 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 LOQ of 1 mg/kg MOAH per MOAH C-fraction is achievable and is a stricter requirement than the LOQ of 2 mg/kg total MOAH

The level of 1 mg /kg MOAH per MOAH C-fraction 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 that shall enable a better estimation of the achievable LOQ in these matrices.

⁶ 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.