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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)

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Abstract

Following the detection of mineral oil aromatic hydrocarbons (MOAH) in batches of infant and follow-on formula in France, Germany and the Netherlands reported by foodwatch, the European Commission (EC) asked Member States (MS) to analyse the concerned batches and to investigate possible contamination sources; and mandated EFSA to perform a rapid assessment on the health risks related to the presence of MOAH in infant and follow-on formula. MOAH may include the presence of genotoxic and carcinogenic 3-7 ring polycyclic aromatic compounds (3-7 PAC). The EFSA opinion of June 2012 on mineral oil hydrocarbons identified a potential health concern related to the presence of these compounds in MOAH. For the current assessment, EFSA received only limited occurrence data from two MS (Austria and Germany), in addition to the data published by foodwatch and data from Specialised Nutrition Europe. Different frequencies of quantifiable MOAH levels were observed, ranging from 50% of detection in the samples tested by foodwatch to lack of detection in the three samples analysed by the German authorities. Quantified MOAH levels were in the range 0.2-3 mg/kg. Due to the complex analytical methods, there is uncertainty on the reported levels which were used to estimate exposure to MOAH for infants and toddlers. Higher levels were estimated for infants, ranging from 0.8 to 44.6 and from 1.7 to 78.8 µg/kg bw per day for average and 95th percentile of exposure, respectively. No information on the absence of 3-7 PAC in the samples analysed was made available to EFSA, and therefore the estimated exposure for infants and toddlers is of possible concern for human health. This assessment relies on occurrence data made available up to 14 November 2019. Analysis of further samples by MS is ongoing and an update of the assessment will be considered upon availability of additional data.

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Key words: mineral oil aromatic hydrocarbon, MOAH, infant formula, follow-on formula, risk, dietary exposure, carcinogenicity

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

1.1.1. Background

In the scientific opinion on mineral oil hydrocarbons in food from the European Food Safety Authority (EFSA), published in 2012, the exposure of consumers to mineral oil hydrocarbons (MOH) was considered to be of potential concern.

The potential human health impact of MOH varies widely. Mineral oil aromatic hydrocarbons (MOAH), in particular 3-7 ring MOAH, may act as genotoxic carcinogens, while some mineral oil saturated hydrocarbons (MOSH) can accumulate in human tissue and may cause adverse effects in the liver.

Following the findings by foodwatch of the presence of MOAH in infant formula and follow-on formula, the Commission services have requested the competent authorities to sample without delay the batches of infant formula and follow-on formula on the presence of MOAH and to perform investigations on the source of contamination.

For the sampling and analysis, the JRC has published a "Guidance on sampling methods, on the performance criteria for the analytical methods and on the reporting of the analytical results" (Bratinova and Hoekstra, 2019).

Member States have been requested to provide without delay the analytical results on the presence of MOAH in infant formula and follow-on formula from the official control referred above directly to EFSA providing details on the levels of different C-fractions and, if possible, the integrated liquid chromatography-gas chromatography-flame ionisation detector (LC-GC-FID) chromatograms of MOSH and MOAH.

EFSA is requested to perform a rapid assessment on the risks for public health related to the presence of MOAH in infant formula and follow-on formula on the basis of the analytical results made available by Member States by 11 November 2019 to EFSA and to present the outcome for discussion at 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.

1.1.2. Terms of Reference

In accordance with Art. 31 of Regulation (EC) No 178/2002, the European Commission asks the European Food Safety Authority to assess the possible risk for public health due to the contamination of infant formula and follow-on formula by MOAH.

1.2. Additional information

MOH are complex mixtures, which are defined as substances of unknown and variable composition (UVCB substances) in the REACH Regulation¹. They consist of three major classes of hydrocarbon compounds, namely (i) straight and branched open-chain alkanes (paraffins), (ii) mostly alkylated cycloalkanes (naphthenes) and (iii) alkylated and non-alkylated aromatics. The latter is defined as MOAH and the first two classes are collectively defined as MOSH (EFSA CONTAM Panel, 2012).

MOH do not encompass the hydrocarbons naturally occurring in food, i.e. n-alkanes of predominantly odd-numbered carbons from C21 to C35, hydrocarbons of terpenic origin, such as squalene, and carotenoids. Polyolefin oligomeric saturated hydrocarbons (POSH), that may be present in food due to migration from plastic packaging (such as polyethylene or polypropylene), are not included in the term MOSH. This fraction is co-eluted during the chromatographic separation with the MOSH fraction and may interfere with the MOSH analysis (Biedermann and Grob, 2012b; Koster et al., 2019). EFSA noted that the fraction consisting of oligomers of polyolefins that are co-eluted with the MOSH fraction includes

¹ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

mono-unsaturated hydrocarbons and thus is also named polyolefin oligomeric hydrocarbons (POH) (Lommatzsch et al, 2015; Bratinova and Hoekstra, 2019).

In this rapid assessment, the following definitions of infant formula and follow-on formula apply:

- Infant formula means food intended for use by infants during the first months of life and satisfying by itself the nutritional requirements of such infants until the introduction of appropriate complementary feeding (Article 2(2)(c) of Regulation (EU) No 609/2013² and Codex Stan 72-1981³).
- Follow-on formula means food intended use by infants when appropriate complementary feeding is introduced and which constitutes the principal liquid element in a progressively diversified diet of such infants (Article 2(2)(d) of Regulation (EU) No 609/2013).

1.2.1. Sources

MOH may enter the food chain via different routes, such as:

- environmental contamination from the air or via the terrestrial or aquatic ecosystem;
- contamination during harvesting and processing from lubricated/oiled machine parts;
- migration from food contact materials;
- use of food additives and pesticides;
- contaminated feed due to the use of refined edible oil, binders for feed additives and waste entering feed.

Due to the numerous potential sources, the source of the contamination is often difficult to identify. A comprehensive review of the sources of MOH in the food chain is presented in the EFSA opinion (EFSA CONTAM Panel, 2012). An overview of the possible contamination sources of infant and follow-on formula is presented in Section 3.3.

1.2.2. Methods of analysis

The analysis of MOH in food is challenging. Current methods are not capable of separating MOH into single compounds with clearly defined peaks. MOH are complex mixtures and chromatograms show irregular and varying humps of largely unresolved components (Biedermann and Grob, 2012b). Separation of MOSH from MOAH can be achieved by LC, which is combined with GC-FID for quantification. The two separation techniques can be combined on-line and off-line (Bratinova and Hoekstra, 2019). At the moment, on-line coupled LC-GC-FID is the method of choice for routine analysis (Biedermann and Grob, 2012a; Biedermann et al., 2017; Weber et al., 2018). However, FID is not selective and sensitive. Careful interpretation by the analysts is a prerequisite and additional sample preparation may be needed to eliminate interferences and to enrich the MOSH and MOAH fractions. In addition, further characterisation of the MOAH and MOSH fractions can be done by gas chromatography-mass spectrometry (GC-MS), LC-GC-FID/MS or comprehensive two-dimensional gas chromatography (GCxGC) with FID/MS detection (Bratinova and Hoekstra, 2019).

The Joint Research Centre (JRC) has developed a guidance on sampling, analysis and data reporting for the monitoring of MOH in food and food contact materials (Bratinova and Hoekstra, 2019). It provides guidance on the minimum performance requirements of the analytical methods used for MOSH/MOAH monitoring and was developed to support the implementation of Commission Recommendation (EU) 2017/84⁴ for the monitoring of mineral oils. The guidance includes a decision

² Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009, OJ L 181, 29.6.2013, pp. 35–56.

³ Codex-Stan 72-1981 (Codex Alimentarius), 2011. Standard for infant formula and formulas for special medical purposes intended for infants. Adopted 1981, amended 1983, 1985, 1987, revised 2007, amended 2011.

⁴ 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.

tree on the use of auxiliary methods, such as epoxidation for removal of natural olefins like squalene, sterene and carotenoids, and clean-up with aluminium oxide to remove odd-numbered natural alkanes with 21 or more carbon atoms. If such auxiliary methods are not adequately applied, an overestimation of MOAH and MOSH level may result from the analyses. The guidance recommends reporting results as subfractions of MOSH and MOAH, the so-called C-fractions. These subfractions are defined by the number of carbon atoms of n-alkanes. However, it should be noted that for the specification of MOAH fractions, retention times corresponding to the carbon number of the n-alkanes in the MOSH fractions are used, despite not matching in terms of carbon numbers for the MOAH fractions (MOAH tend to be eluted later, i.e. their number of carbon atoms tends to be lower, depending on the number of rings and the alkylation).

1.2.3. Previous EFSA risk assessment of MOAH in food

In the EFSA opinion on MOH (EFSA CONTAM Panel, 2012), it was not possible to draw conclusions on the risks related to the presence of MOAH in food, due to the insufficient data on the exposure levels available at the time, and in particular to the impossibility of establishing a toxicological reference point to characterise the hazards. In view of the high complexity of the MOAH mixtures relevant to dietary exposure, the CONTAM Panel considered that it was not adequate to base the hazard characterization on individual components. On the other hand, dose-response data were not available for relevant MOAH mixtures. Based on hazard identification data on single substances and MOAH mixtures the Panel could only make qualitative conclusions on the possible hazards of MOAH. In particular, 3-7 ring MOAH with no alkylation or low degree of alkylation were identified as the components of main concern in view of their genotoxic and carcinogenic nature. MOAH with high degree of alkylation are not carcinogens but they can act as tumour promoter following initiation with a genotoxic substance in skin painting studies in mice. Finally, some MOAH with less than three rings like naphthalene could still act as carcinogens via non genotoxic modes of action, involving cytotoxicity and regenerative cell proliferation. At the time of the opinion, the dietary exposure assessment allowed only to estimate a possible contribution ranging between 15 and 35% of MOAH to the overall MOH exposure. No information was available on the composition of the MOAH detected in food. In this complex picture, the CONTAM Panel concluded that in view of the possible presence of genotoxic and carcinogenic substances, the dietary exposure to MOAH is to be considered of potential concern.

1.2.4. Previously reported occurrence of MOAH in infant formula

EFSA conducted a literature search to identify studies on the occurrence of MOH in infant formula and follow-on formula published since the previous EFSA opinion. Two recent papers reporting the analyses of samples collected in China were identified.

Zhang et al. (2019) analysed 50 commercial milk powder products, of which 38 were intended for infants and young children, with on-line LC-GC-FID (limit of quantification (LOQ)=0.1 mg/kg); no confirmatory method was applied. MOAH was not detected in any of the samples. Out of the 38 samples that were intended for infants and young children, MOSH was detected in six products packaged in metal cans and in all products packaged in paper (n=18).

Zhu et al. (2019) reported the analysis of 115 samples of infant formula, follow-up formula and young children formula.⁵ Off-line separation of MOSH/MOAH was followed by analysis by GC-FID or GC-MS (LOQ for MOAH was 0.5 mg/kg). MOAH was detected in 10 out of 42 infant formula samples (concentration range: <0.5-6.65 mg/kg), in 17 out of 38 follow-up infant formula samples (<0.5-17.35 mg/kg) and 9 out of 35 young children formula samples (<0.5-2.27 mg/kg).

1.2.5. Presence in food

In the previous EFSA opinion (EFSA CONTAM Panel, 2012) only limited data were available on the levels of MOAH detected in food. Based on the experience of the main occurrence data submitter, the Kantonal Labor Zurich, MOAH were estimated to contribute from 15 to 35% to the levels of MOH detected in various foods.

⁵ The authors defined infants as 0 to 6 months of age, follow-up infants as 7 to 12 months of age and young children as 13 to 36 months of age.

Assuming an indicative MOAH contribution of 20% to the MOH levels across foods, mean MOAH levels of approximately 9 mg/kg could be found in vegetable oils, or 2 mg/kg in grain milling products.

Estimated exposure to total MOH in adolescent and adult age groups ranged from 0.03 to 0.10 and from 0.06 to 0.2 mg/kg bw per day for average and high (95th percentile; P95) consumption, respectively. In the younger age groups, mean and P95 exposure ranged from 0.04 to 0.19 and from 0.14 to 0.32 mg/kg bw per day, respectively (EFSA CONTAM Panel, 2012).

Considering the aforementioned indicative presence of 20% MOAH in MOH across different foods, exposure to MOAH based on the 2012 estimations would be in the range 6–40 µg/kg bw per day for average consumption and 12–64 µg/kg bw per day for P95 consumption across all age groups.

Following the EC Recommendation (EU) 2017/84⁶ on the monitoring of MOH in food and food contact materials, additional data are being submitted to EFSA on the levels on MOAH in food, which can be used to update the exposure assessment performed in 2012.

2. Data and Methodologies

2.1. Occurrence data submitted to EFSA

Based on Commission Recommendation (EU) 2017/84 on the monitoring of mineral oil hydrocarbons in food and in materials and articles intended to come into contact with food, Member States, food business operators, manufacturers, processors and distributors of food contact materials and other interested parties have been recommended to provide EFSA with analytical results on the presence of MOAH in infant formula and follow-on formula, providing details on the levels of fractions separated by number of carbon atoms and, if possible, the integrated LC-GC-FID chromatograms of MOSH and MOAH, in line with the above mentioned JRC guidance.

Data on MOAH in infant formula and follow-on formula submitted to EFSA by 14 November 2019 were considered for the present assessment.

2.2. Food consumption data

The EFSA Comprehensive European Food Consumption Database (hereinafter referred to as the Comprehensive Database) provides a compilation of existing national information on food consumption at the individual level. It was first built in 2010 (EFSA, 2011b; Huybrechts et al., 2011; Merten et al., 2011). Details on how the Comprehensive Database is used have been published in the Guidance of EFSA (EFSA, 2011b). The latest version of the Comprehensive Database, updated in 2018⁷, contains results from a total of 60 different dietary surveys carried out in 25 different Member States covering 119,458 individuals.

Within the dietary studies, subjects are classified in different age classes. Since this assessment was only related to the consumption of infant formula and follow-on formula, only the following age classes were considered:

Infants: (< 12 months old)

Toddlers (≥ 12 months to < 36 months old)

Consumption data were collected using single or repeated 24- or 48-hour dietary recalls or dietary records covering three to seven days per subject. Owing to the differences in the methods used for data collection, direct country-to-country comparisons can be misleading.

Detailed information on the different dietary surveys used in this report is given in Annex A Table A.1, including the number of subjects and days available for each age class.

In addition, the EFSA Scientific Committee (2017) noted that during the period from birth up to 16 weeks, infants are expected to be exclusively fed on breast milk and/or infant formula. The Committee recommended assessment of the exposure to substances with a long half-life that accumulate in the

⁶ 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.

⁷ <http://www.efsa.europa.eu/en/food-consumption/comprehensive-database>

body to select appropriate consumption values representing a longer period of feeding, i.e. 170 (P50) and 210 (P95) mL/kg bw per day.

2.3. Food classification

Consumption data were classified according to the FoodEx classification system (EFSA, 2011a). FoodEx is a food classification system that was developed by EFSA in 2009 with the objective of simplifying the linkage between occurrence and food consumption data when assessing the exposure to hazardous substances. The system consists of a large number of individual food items aggregated into food groups and broader food categories in a hierarchical parent–child relationship. It contains 20 main food categories (first level), which are further divided into subgroups with 140 items at the second level, 1,261 items at the third level and reaching about 1,800 endpoints (food names or generic food names) at the fourth level.

2.4. Exposure assessment

As suggested by the EFSA Working Group on Food Consumption and Exposure (EFSA, 2011b), dietary surveys with only one day per subject were not considered as they are not adequate for assessing repeated exposure. Similarly, subjects who participated in the dietary studies for only one day when the protocol prescribed more reporting days per individual were also excluded for the chronic exposure assessment. When, for one particular country and age class, two different dietary surveys were available, only the most recent one was used.

Thus, for the current chronic exposure assessment, food consumption data were used from 14 different and most recent dietary surveys carried out in 13 different European countries present in the latest version of the Comprehensive Database (Annex A, Table A.1).

To estimate chronic dietary exposure to MOAH, food consumption and body weight data at the individual level were accessed in the Comprehensive Database. Occurrence data and consumption data were linked at the level of infant formula (powder) and follow-on formula (powder). Consumption events of infant formula (liquid) and follow-on formula (liquid) were transformed into powder by using a factor of 8, as suggested in the EFSA Internal Report on the harmonisation of dilution factors to be used in the assessment of dietary exposure (EFSA, 2018).

Considering that the variability of MOAH levels in different brands and/or batches of infant formula and follow-on formula is unknown, and that infants and toddlers are expected to regularly consume the same brand, and in the short term even the same batch, mean occurrence levels for MOAH were not used for the assessment of chronic exposure. Instead, different scenarios were assessed based on the minimum and maximum quantified analytical results received from the different data providers.

Under each scenario, the mean and high (P95) chronic dietary exposures were calculated by combining MOAH values for infant formula and follow-on formula with the average daily consumption for each food at individual level in each dietary survey and age class. Consequently, individual average exposures per day and kg body weight were obtained for all individuals. Based on distributions of individual exposures, the mean and P95 exposure were calculated per survey and per age class. For each age group and dietary survey, the mean and P95 of exposure were estimated among consumers only of infant formula and follow-on formula.

In addition, exposure was also estimated on the basis of the default consumption values for infant formula (P50: 170 mL/kg bw per day and P95: 210 mL/kg bw per day) recommended by the EFSA Scientific Committee for assessing the exposure in the period from birth up to 16 weeks (EFSA Scientific Committee, 2017).

All analyses were run using the SAS Statistical Software (SAS enterprise guide 9.4).

2.5. Hazard identification and characterisation, and risk characterisation

Given the short deadline of this urgent request, the previous assessment on MOH carried out by the CONTAM Panel (EFSA CONTAM Panel, 2012) was used as the basis of the current rapid risk assessment. No additional search for scientific literature related to the hazard identification and characterisation was

conducted. EFSA applied the general principles of the risk characterisation process for chemicals in food as described by WHO/IPCS (2009) and the relevant EFSA guidance documents.

2.6. Supporting information for the assessment

A literature search was conducted to identify information on the occurrence of MOAH in infant formula and follow-on formula and recent reviews on the analysis of MOH in food. The search strings used are presented in Appendix A.

3. Assessment

3.1. Considerations on possible sources of exposure

The presence of MOAH in food is of concern due to the potential presence of genotoxic and carcinogenic substances identified as 3-7 polycyclic aromatic compounds (3-7 PAC). The detection of this fraction within the MOAH present in food requires elaborated analytical techniques, such as GCxGC-FID/MS. Tracing back the source and nature of contamination could also be an effective way to further characterise the toxicological profile of the MOAH detected in a specific food.

Considering the potential sources of contamination identified in 2012 by the CONTAM Panel, it is plausible to assume that MOAH may end up in infant and follow-on formula either i) from environmental contamination of one or more ingredients present in the formula, or ii) during the processing of the ingredients at the food manufacturing level, or iii) from the transfer from food contact materials.

i) Environmental contamination occurs via several sources, for instance from the use of MOAH-containing products such as lubricants in e.g. harvesting machines or motor oils in diesel engines, as well as from unburnt fuels or bitumen and tyre debris.

ii) Lubricants and release agents used in food industry can also contribute to food contamination with MOAH. However, food grade lubricants and release agents based on “white” oils (virtually MOAH-free) are expected to be used by the food industry when contact with food is likely. MOAH-containing fluids could still be present in the machine parts not intended to have close contact with food (e.g. pump fluids) and possible leakage could result in MOAH contamination.

iii) The infant and follow-on formula analysed in the foodwatch project were all packaged in metal cans. Since MOH are also used as lubricating agent during the can production, this was suggested by foodwatch as a possible source of contamination. More in general, transfer from other materials used before the final packaging could have also contributed, notably the use of jute bags for shipping raw materials (e.g. oilseeds) used for producing ingredients of infant and follow-on formula. Finally, MOAH-containing products are also present in other materials for possible contact with food, such as printing inks, adhesives and sealants.

The likelihood of the presence of the genotoxic and carcinogenic 3-7 PAC fraction in the MOAH detected in food depends on the contamination sources as discussed below.

For example, possible environmental contaminants such as fuels and bitumen are crude oil distillation products which contain MOAH, possibly including 3-7 PAC. Distillate aromatic extracts (DAE) are used in rubber manufacturing including tyres. These products are extracts of crude oil with a high 3-7 PAC component. Since 2010, the use of DAE in tyre manufacturing is not allowed in the EU according to Directive 2005/69/EC⁸, however some replacement products (treated DAE (TDAE)) may still contain residual levels of 3-7 PAC. Overall, these types of environmental sources are expected to contribute to the background levels of MOAH in food.

Other products for industrial, professional and/or consumer uses, such as lubricants, mechanical fluids or other processing aids are formulated from an extensive series of MOH substances registered under REACH and officially classified in the EU CLP Regulation (EC) No 1272/2008⁹ (see example from the ECHA website¹⁰). Under a common scheme, these substances are classified under the CLP Regulation as possible human carcinogens (Carcinogen 1B), unless it can be shown that the substance contains

⁸ Directive 2005/69/EC of the European Parliament and of the Council of 16 November 2005 amending for the 27th time Council Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (polycyclic aromatic hydrocarbons in extender oils and tyres)

⁹ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and 3-7 PACking of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

¹⁰ <https://echa.europa.eu/it/substance-information/-/substanceinfo/100.059.214>

less than 3% dimethyl sulphoxide extract, as measured by the IP 346 method¹¹ developed by the petrochemical industry. Based on this information, it can be concluded that products formulated with MOAH-containing substances meeting the IP 346 standards will not contain appreciable amounts of 3-7 PAC, and therefore food contamination with these substances should not be of high concern for genotoxic and carcinogenic risks. However, from the information reported in the REACH Registration dossiers it is unclear whether untreated or ineffectively treated substances (i.e. not meeting IP 346 criteria) are currently placed in the market for applications that could result in food contamination.

3.2. Occurrence data

The present assessment relies on occurrence data made available to EFSA by 14 November 2019. An update of the assessment will be considered upon availability of additional data.

3.2.1. Occurrence data reported by foodwatch

On 24 October 2019, foodwatch published the results from the analysis of 16 samples of infant formula and follow-on formula packaged in cans on their website¹². Samples had been collected in France, Germany and the Netherlands during the last week of July and the first week of August 2019. Analysis was performed using online LC-GC-FID and results were verified using GCxGC-MS. MOAH was quantified in eight samples (LOQ = 0.5 mg/kg) and concentrations ranged from 0.5 to 3.0 mg/kg.

Following a request for additional information to foodwatch, EFSA received further information on the analytical methods and the analytical results by subfraction; the so-called C-fractions. In the three samples with the highest MOAH concentration (1.6-3.0 mg/kg), the subfractions >C25-≤C35 and >C35-≤C50 were detected and the latter was the major. In the other five samples (0.5-1.2 mg/kg), only the subfraction >C35-≤C50 was detected. The percentage of MOAH from the total MOH was 25-27% in the three samples with the highest MOAH concentration. In the other samples, it ranged between 12 and 17%.

3.2.2. Occurrence data reported by SNE

Specialised Nutrition Europe (SNE) provided EFSA with 798 analytical results for different MOAH fractions related to 696 samples of infant and follow-on formula, in powder and liquid. Most samples (624) were analysed for only one MOAH fraction, 42 and 30 samples were analysed for two and three MOAH fractions, respectively. These samples were collected between 2016 and 2019. The analytical methods used were LC-GC-FID/(HR)MS and LC-GC-FID, and a few samples were analysed with GC-FID or an unspecified internal method. For a part of the samples analysed by LC-GC-FID, it was indicated that this was done by an accredited laboratory. The reported limits of detection (LODs) ranged from 0.05 to 0.5 mg/kg and the LOQs from 0.15 to 1 mg/kg.

The data submission to EFSA did not follow the requirements of the EFSA Guidance on Standard Sample Description for Food and Feed (EFSA, 2010).

In the dataset provided by SNE, a MOAH fraction was detected in 28 out of 677 samples of infant formula-powder (4%), with the highest result found for MOAH C25-C35 in infant formula-powder equal to 1.6 mg/kg. MOAH fractions were not detected in infant formula-liquid (13 samples) and follow-on formula-liquid (6 samples). EFSA noted that for several samples, and for all samples with a quantified concentration at or above 1 mg/kg, it was indicated that natural interferences were present in the MOAH region.

Out of the 28 positive samples of infant formula-powder, eight were analysed for two MOAH fractions (MOAH C16-C25 and C25-C35). All eight samples were positive for MOAH C25-C35 and left censored

¹¹ IP (1993) Determination of polycyclic aromatics in unused lubricating base oils and asphaltene free petroleum fractions - dimethyl sulphoxide extraction refractive index method. IP 346192. In: Standard methods for analysis and testing of petroleum and related products Vol 2. Chichester: John Wiley and Sons.

¹² <https://www.foodwatch.org/en/news/2019/foodwatch-laboratory-tests-suspected-carcinogenic-mineral-oil-residues-in-baby-milk/>

for MOAH C16-C25. Seven samples were positive for the MOAH C10-C62 and 13 samples were positive for C10-C35.

More information on the occurrence data provided by SNE are presented in Annex A, Table A.2.

3.2.3. Occurrence data reported by Member States

The European Commission requested Member States to submit analytical results on MOAH in infant formula and follow-on formula to EFSA by 11 November 2019. No results were received from Member States by this deadline. However, the Austrian Agency for Health and Food Safety (AGES) submitted the analytical results of four samples in SSD2 format on 13 November 2019. The results relate to three samples of follow-on formula and one sample of infant formula. For each sample, the online LC-GC-FID method with a LOQ of 0.5 mg/kg was used and results were reported by C-fraction. Only in one sample of follow-on formula was MOAH >C35 to ≤ C50 detected at a level of 1 mg/kg. The analysis was performed following DIN EN 16995:2017.¹³

In addition to the occurrence data submitted by AGES, the Federal Office of Consumer Protection and Food Safety (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit; BVL) reported on 12 November 2019 in the rapid alert system for food and feed (RASFF) the results of two samples analysed as self-control by Nestlé and three samples taken within the official control. Self-control analyses of Nestlé's reserve samples of the two products for which foodwatch reported the highest concentrations showed no detectable levels of MOAH. It should be noted that the batch numbers and expiration dates corresponded to the batch numbers and expiration dates analysed by foodwatch. The three samples taken within the official control were from products analysed by foodwatch but for which a different batch was sampled. No MOAH were detected. On 14 November 2019, the analysis reports of these five samples (i.e. two of self-control and three of official controls) were made available. The self-control analyses of Nestlé's reserve samples were carried out by an external laboratory. The applied analytical techniques were LC-GC-FID (accredited method; LOD=0.05 mg/kg) and LC-GC-HRMS (accredited method). The analysis of the three samples from official control was performed using online LC-GC-FID according to the method DIN EN 16995:2017. All MOAH C-fractions were < 0.1 mg/kg.

The Netherlands reported on 14 November 2019 in the RASFF that Nutricia analysed the reserve sample of Nutrilon belonging to the same batch as the sample analysed by foodwatch. No MOAH was detected. In addition, Nestlé analysed the reserve sample of Nestlé Nidal belonging to the same batch as the sample analysed by foodwatch. No MOAH was detected. No information was provided regarding the analytical method used and the performance of the method.

Other Member States indicated to EFSA that analysis of samples is ongoing and that results will be submitted to EFSA as soon as they will become available.

3.2.4. Considerations on the available occurrence data

Following the findings by foodwatch, the Commission services requested the competent authorities to sample the same batches of infant formula and follow-on formula on the presence of MOAH. Results of self-control analyses of four reserve samples by food business operators were negative (i.e. no MOAH detected). These differences could be due to variability within the batch or to an issue with the analytical method.

Differences were observed in the C-fractions reported and the C-fractions for which quantifiable results were obtained. AGES and foodwatch reported the results by C-fraction as specified in the JRC guidance document. For the samples reported by SNE, not all C-fractions were reported. Analysis of the results by C-fraction showed that the positive sample reported by AGES contained the >C35 to ≤ C50 fraction. Also in the results reported by foodwatch, this was the major fraction and only in the samples with the highest MOAH concentration was the fraction >C25-≤C35 detected. The samples reported by SNE were only quantifiable for the MOAH fractions C10-C35, C10-C62 and C25-C35.

In addition, differences were observed in the frequency of measuring quantifiable MOAH levels. Foodwatch quantified MOAH in 8 out of 16 samples of infant and follow-on formula (50%), AGES in 1

¹³ Foodstuffs - Vegetable oils and foodstuff on basis of vegetable oils - Determination of mineral oil saturated hydrocarbons (MOSH) and mineral oil aromatic hydrocarbons (MOAH) with on-line HPLC-GC-FID analysis; German version EN 16995:2017

out of 4 (25%), SNE in 28 out of 696 (4%) and BVL in 0 out of 3 (0%). It should be noted that the timeframe of sampling was different. Although differences were observed in the frequency of measuring quantifiable MOAH levels between the different datasets, the reported concentrations were in the same order of magnitude. AGES reported a quantified result of 1 mg/kg, SNE reported quantified results ranging from 0.2 to 1.6 mg/kg, and foodwatch from 0.5 to 3 mg/kg. Based on these observations, EFSA decided to calculate the dietary exposure based on the minimum and maximum quantified results, i.e. 0.2 and 3 mg/kg.

It should be noted that these concentrations of MOAH were calculated following a lower bound approach, i.e. when fractions were not analysed or not detected, a concentration of 0 mg/kg was assumed.

EFSA received no chromatograms of the analyses generated by means of the LC-GC-FID and GCxGC-FID/MS methods. GCxGC analysis enables the separation of the MOAH by ring number, in particular the determination of the 3-7 PAC. In the absence of such chromatograms, no conclusion can be drawn regarding the presence of the 3-7 PAC. Foodwatch indicated that, due to a contractual agreement, the identity of the participating laboratories could not be disclosed and the original laboratory reports including chromatograms could not be made publicly available. However, foodwatch reported that they will liaise with the laboratories to enquire whether the chromatograms can be made available to EFSA on a confidential basis.

3.3. Dietary exposure assessment for infants and toddlers

Table 1 summarises the chronic dietary exposure estimates for MOAH across the 14 dietary surveys. Detailed summary statistics on the exposure estimates calculated for each dietary survey are presented in Annex A, Table A.1. Based on the maximum quantified concentration of MOAH (3 mg/kg), the exposure to MOAH in consumers of infant formula and follow-on formula was higher for infants, with mean and P95 exposure estimates ranging from 12.3 to 44.6 µg/kg bw per day and from 25.9 to 78.8 µg/kg bw per day, respectively.

On the basis of the default consumption values for infant formula recommended by the EFSA Scientific Committee (2017) in the period from birth up to 16 weeks of age, median and P95 exposure were equal to 4 and 5 µg/kg bw per day respectively, based on the minimum quantified concentration of MOAH, and 64 and 79 µg/kg bw per day respectively, based on the maximum quantified concentration of MOAH.

Table 1: Mean and 95th percentile of chronic dietary exposure estimates for MOAH in consumers of infant formula and follow-on formula under different assumptions for MOAH concentrations.

	Infants			Toddlers		
	No. of surveys	Min	Max	No. of surveys	Min	Max
Based on the minimum quantified concentration of MOAH^(a) (0.2 mg/kg)						
Mean exposure (µg/kg bw day)	11	0.8	3.0	14	0.4	0.9
P95 exposure (µg/kg bw day)	9	1.7	5.3	6	1.1	1.8
Based on the maximum quantified concentration of MOAH^(a) (3 mg/kg)						
Mean exposure (µg/kg bw day)	11	12.3	44.6	14	6.4	13.4
P95 exposure (µg/kg bw day)	9	25.9	78.8	6	16.2	27.2

Max: maximum; Min: minimum; MOAH: mineral oil aromatic hydrocarbons; No.: number; P95: 95th percentile

(a): Considering data received from Member States, foodwatch and Specialised Nutrition Europe (SNE)

3.4. Considerations on hazard identification and characterization

In relation to the possible presence of genotoxic and carcinogenic 3-7 PAC in MOAH, this statement confirms the conclusions of the previous EFSA opinion (EFSA CONTAM Panel, 2012) that it is not possible to characterise the hazard in the absence of relevant dose-response data. The classification of MOH as possible human carcinogens is based on hazard identification studies (skin painting studies in mice), which cannot be used for the derivation of an oral reference point relevant for hazard characterization. Therefore, in the absence of any additional information on the presence of 3-7 PAC, the detection of MOAH in food should be considered of possible concern for human health. In addition to these considerations, it is noted from the category approach proposed in the REACH Registration dossiers that oral toxicity studies are hardly available and a full toxicological characterization of the MOAH-containing substances is lacking. Therefore, even if there was enough information to exclude the presence of 3-7 PAC in food, the characterization of possible non-neoplastic hazards would not be feasible.

3.5. Risk characterisation

Dietary exposure was calculated using the minimum and maximum quantified concentration of MOAH in infant formula and follow-on formula based on data received from Member States, foodwatch and SNE. For infants, the mean dietary exposure estimates ranged from 0.8 to 44.6 µg/kg bw per day, and the P95 from 1.7 to 78.8 µg/kg bw per day. For toddlers, the dietary exposure estimates were lower; the mean dietary exposure estimates ranged from 0.4 to 13.4 µg/kg bw per day and the P95 from 1.1 to 27.2 µg/kg bw per day.

These exposure estimates are based on limited information. Due to the complexity of the analytical methods for MOAH in food, there is uncertainty related to the levels found. No additional information on the presence of 3-7 PAC in the samples analysed was made available to EFSA. Considering the possible presence of 3-7 PAC in the MOAH, the estimated exposure for infants and toddlers is of concern for human health.

4. Conclusions

- Contamination of infant and follow-on formula, and more in general of food, with MOAH can originate from different sources either via the environment, during industrial food manufacturing and processing, or via transfer from food contact materials.
- 3-7 PAC are MOAH components of main concern for their genotoxic and carcinogenic nature.
- The likelihood of the presence of the genotoxic and carcinogenic 3-7 PAC in the MOAH detected in food depends on the contamination sources.
- Possible environmental contamination may be associated with the presence of 3-7 PAC. Products for industrial, professional and/or consumer uses, such as lubricants, are formulated from MOAH-containing substances. For these, standards established by the petrochemical industry (IP 346) have been used to define MOAH-containing substances without appreciable amounts of 3-7 PAC. Food contamination with these substances should not be of high concern for genotoxic and carcinogenic risks.
- In relation to the possible presence of genotoxic and carcinogenic 3-7 PAC in MOAH, this rapid risk assessment confirms the conclusions of the previous EFSA Opinion on MOH in food that it is not possible to characterise the hazards in the absence of relevant dose-response data. Therefore, in the absence of any additional information on the presence of 3-7 PAC, the detection of MOAH in food should be considered of potential concern for human health.
- In addition, due to the lack of a full toxicological characterization of MOAH-containing substances, even if there was enough information to exclude the presence of 3-7 PAC in food, the characterization of possible non-neoplastic hazards would not be feasible.
- EFSA received occurrence data from Member States, foodwatch and SNE. Differences were observed in the frequency of measuring quantifiable MOAH levels. Foodwatch quantified MOAH in 8 out of 16 samples of infant and follow-on formula, AGES in 1 out of 4, SNE in 28 out of 696 and BVL in 0 out of 3. However, concentrations were in the same order of magnitude when MOAH was detected, ranging from 0.2 to 3 mg/kg.

- Analysis by food business operators of four reserve samples, belonging to the same batch as analysed by foodwatch, were negative (i.e. no MOAH detected).
- Four positive results reported by foodwatch were not confirmed by food business operators on the basis of self-analyses of reserve samples belonging to the same batches as those analysed by foodwatch.
- Dietary exposure was estimated for infants and toddlers using the minimum and maximum quantified concentration of MOAH in infant formula and follow-on formula.
- Dietary exposure was highest for infants, with mean exposure estimates ranging from 0.8 to 44.6 µg/kg bw per day, and P95 estimates ranging from 1.7 to 78.8 µg/kg bw per day.
- These exposure estimates are based on limited information. Due to the complexity of the analytical methods for MOAH in food, there is uncertainty related to the levels found. No additional information on the presence of 3-7 PAC in the samples analysed was made available to EFSA. Considering the possible presence of 3-7 PAC in the MOAH, the estimated exposure for infants and toddlers is of concern for human health.

5. Recommendations

- 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.
- To perform quantitative risk assessment related to the dietary exposure to MOAH, relevant data should be generated to identify and characterise the hazards of MOAH. This should not be limited to the assessment of the carcinogenic risks but should include the identification and characterization of any hazard relevant to human health.

Documentation provided to EFSA

1. Additional information on the methodology applied in the laboratory tests reported by foodwatch on 24 October 2019, as well as the analytical results by subfraction (so-called C-fractions). 8 November 2019. Submitted by foodwatch.

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Abbreviations

3-7 PAC	3-7 ring polycyclic aromatic compounds
AGES	Austrian Agency for Health and Food Safety
BVL	Bundesamt für Verbraucherschutz und Lebensmittelsicherheit; Federal Office of Consumer Protection and Food
DAE	distillate aromatic extracts
FID	flame ionisation detector
GC	gas chromatography
GCxGC	two-dimensional gas chromatography
HRMS	High resolution mass spectrometry
JRC	Joint Research Centre
LC	liquid chromatography
LOD	limit of detection
LOQ	limit of quantification
MOAH	mineral oil aromatic hydrocarbons
MOH	mineral oil hydrocarbons
MOSH	mineral oil saturated hydrocarbons
MS	mass spectrometry
P95	95th percentile
POH	polyolefin oligomeric hydrocarbons
POSH	polyolefin oligomeric saturated hydrocarbons
RASFF	rapid alert system for food and feed
SNE	Specialised Nutrition Europe
TDAE	treated distillate aromatic extracts

Appendix A – Literature search to identify additional information for the assessment

A. Pubmed

Used search string: ((mineral oil hydrocarbon OR mineral oil aromatic hydrocarbons OR MOAH OR MOH)) AND (infant formula OR follow-on formula OR baby food OR milk powder)

Results: 34

Used search string: (((((mineral oil hydrocarbon OR mineral oil aromatic hydrocarbon)) AND (analysis OR analytical)) AND review) AND (food OR infant formula)) AND ("2014/01/01"[Date - Publication] : "3000"[Date - Publication])

Results: 5

B. Web of science

Used search string: TOPIC: (mineral oil hydrocarbon OR mineral oil aromatic hydrocarbon OR MOAH OR MOH) *AND* TOPIC: (infant formula OR follow-on formula OR baby food OR milk powder); *Databases= WOS, BCI, CABI, CSCD, CCC, DRCI, FSTA, KJD, MEDLINE, RSCI, SCIELO, ZOOREC Timespan=All years; Search language=Auto*

Results: 34

Used search string: TOPIC: (mineral oil hydrocarbon OR mineral oil aromatic hydrocarbon) *AND* TOPIC: (analysis OR analytical) *AND* TOPIC: (review) *AND* TOPIC: (food OR infant formula); *Databases= WOS, BCI, CABI, CSCD, CCC, DRCI, FSTA, KJD, MEDLINE, RSCI, SCIELO, ZOOREC Timespan=Last 5 years; Search language=Auto*

Results: 26

Annex A – Summary of the occurrence data submitted by SNE, dietary surveys and exposure estimates

See the attached excel file.