

# Trying to Run Before You Can Walk: Control and Enforcement of Mineral Oil Aromatic Hydrocarbon Contamination of Food in the European Union

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*The current agreement between European Union ('EU') Member States to withdraw or recall food products in which a quantified presence of the contaminant mineral oil aromatic hydrocarbons ('MOAH') is confirmed may soon be replaced by EU legislation establishing maximum levels of MOAH in food. Both initiatives will likely lead to significant business interruption of global supply chains for a wide range of food products in which MOAH concentrations are detected. This article critically assesses the harmonised EU enforcement approach to MOAH contamination of food and finds it to be questionable from both a legal and scientific perspective.*

Mineral oil hydrocarbons ('MOH') are chemical compounds derived mainly from crude oil but also produced synthetically from coal, natural gas, and biomass. They are present as contaminants in food through a variety of sources, including harvesting or food processing machinery lubricants, processing aids (such as dust binders), food additives, food contact materials or environmental contamination. They can be divided into two categories: mineral oil saturated hydrocarbons ('MOSH') and mineral oil aromatic hydrocarbons ('MOAH'). This article concerns only MOAH, which compounds, in contrast to MOSH, comprise at least one aromatic ring (carbon atoms arranged in the form of a hexagon).<sup>1</sup>

## I. Chronological Overview of Recent Developments

The last two years have seen a number of further developments at European Union ('EU') level concerning the control and enforcement of possible health risks resulting from contamination of food with mineral oil aromatic hydrocarbons ('MOAH') which have significant regulatory compliance implications for food business operators ('FBOs') active on the EU market.

At a meeting of the Standing Committee on Plants, Animals, Food and Feed ('SCoPAFF'), Section Novel Food and Toxicological Safety of the Food Chain on 21 April 2022<sup>2</sup> ('the April 21 2022 SCoPAFF meeting'), the Committee (EU Member States and the European Commission) agreed upon a Joint Statement regarding the presence of MOAH in food<sup>3</sup> ('the Joint Statement'). In this Joint Statement, which was later clarified in a subsequent SCoPAFF meeting on 19 October 2022 ('the 19 October 2022 SCoPAFF meeting'),<sup>4</sup> EU Member States agreed to withdraw or recall from the market (on the basis of Article 14 of Regulation (EC) No 178/2002 laying down the general principles of food law ('Regulation (EC) No 178/2002')) those foods in which the sum of MOAH concentrations (covering the fraction of C<sub>10</sub>-C<sub>50</sub>) is confirmed by official controls as meeting or exceeding the following relevant maximum limits of quantification ('LOQs'):

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1 For example, see the European Food Safety Authority webpage on Mineral Oil Hydrocarbons, last updated 13 September 2023, <<https://www.efsa.europa.eu/en/topics/topic/mineral-oil-hydrocarbons>>.

2 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, 21 April 2022, sante.ddg2.g.5(2022)3966048.

3 Draft joint statement of the Member States regarding the presence of Mineral Oil Aromatic Hydrocarbons ('MOAH') in food, including food for infants and young children.

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, 19 October 2022, sante.g.3(2022)8681453.

0.5mg/kg for dry foods with a low fat/oil content ( $\leq 4\%$  fat/oil);

1 mg/kg for foods with a higher fat/oil content ( $> 4\%$  fat/oil,  $\leq 50\%$  fat/oil); and

2 mg/kg for fats/oils or foods with  $> 50\%$  fat/oil.

The responsibility of FBOs to withdraw and recall their products in accordance with Article 19 of the Regulation (EC) No 178/2002 where their own controls reveal the quantifiable presence of MOAH in food was also emphasised.

The Joint Statement further stated that both EU Member States and FBOs should perform controls on the presence of MOAH in microcrystalline wax and its potential migration into food, including through its use in food contact materials, and take, if necessary, measures to prevent the occurrence of MOAH in food. It should also be checked whether microcrystalline wax used in food contact materials is claimed to be E905 (microcrystalline wax authorised for specific food additive uses) and, if this is the case, whether it complies with the specifications of E905, in particular as regards the presence of benzo[a]pyrene (a MOAH).

In the 19 October 2022 SCoPAFF meeting, the Commission indicated that it would evaluate whether changes were needed regarding the requirements for certain additives or food contact materials once an updated European Food Safety Authority ('EFSA') opinion on MOH was available.

In early 2023, the European Commission's Joint Research Centre published the anticipated second edition of its Guidance on sampling, analysis and data reporting for the monitoring of MOH in food and food contact materials<sup>5</sup> ('the updated JRC Guidance') specifying minimum performance requirements for the analytical methods to be used for MOAH monitoring and control.

On 12 July 2023, EFSA adopted an update of the risk assessment of mineral oil hydrocarbons in food<sup>6</sup> ('EFSA's updated risk assessment'). In this Opinion, EFSA found that new studies confirmed the conclusions of a previous 2012 EFSA Opinion that genotoxicity and carcinogenicity are associated with MOAH with three or more aromatic rings.<sup>7</sup> In contrast, a risk characterisation for MOAH with one or two aromatic rings could not be performed due to a lack of reliable toxicity data, leading EFSA to conclude only that 'dietary exposure to 1–2 ring MOAH might raise a concern'.<sup>8</sup> EFSA emphasised the need for more data on MOAH composition by aromatic

ring number in food (since MOAH substances are not believed to have equal toxicity), in particular regarding levels of MOAH with three or more aromatic rings, and on oral toxicity, in particular with respect to MOAH with one or two aromatic rings. It further recommended that the sources of food contamination be investigated when MOAH are detected, and that technical specifications of white mineral oils and waxes used as food additives and food packaging materials be updated with detailed information about their MOAH content and composition.<sup>9</sup>

In late 2023, the Commission's Directorate-General for Health and Food Safety ('DG SANTE') circulated to stakeholders a draft Commission Regulation amending Regulation (EU) 2023/915<sup>10</sup> as regards maximum levels of MOAH in food<sup>11</sup> ('draft Regulation setting maximum levels of MOAH in food') with an accompanying discussion paper,<sup>12</sup> a discussion paper regarding a monitoring recommendation on MOH in food and a draft Commission Implementing Regulation amending Regulation (EC) No 333/2007<sup>13</sup> as regards the methods of sampling and analysis for the control of levels of MOH in foodstuffs.<sup>14</sup> The draft Regulation setting maximum levels of MOAH in food proposes establishing maximum MOAH levels at the LOQ, except for foods for which industry demonstrates that, pursuant to current best available practices, MOAH concentrations below the LOQ cannot be achieved. For those foods, maximum levels above the LOQ should be set which should subsequently be lowered in accordance with

5 JRC Technical Reports, Guidance on sampling, analysis and data reporting for the monitoring of mineral oil hydrocarbons in food and food contact materials – 2<sup>nd</sup> Edition, In the frame of Commission Recommendation (EU) 2017/84, S. Bratinova, P. Robouch, E. Hoekstra, 2023.

6 EFSA Scientific Opinion, doi:10.2903/j.efsa.2023.8215.

7 EFSA's updated risk assessment, Abstract, p. 1.

8 Ibid., Section 4.3., p. 95.

9 Ibid., Section 5., p. 96.

10 Regulation (EU) 2023/915 on maximum levels for certain contaminants in food.

11 SANTE PLAN 2023/2345 Rev.1.

12 Discussion paper as regards maximum levels for MOAH in food.

13 Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs.

14 SANTE PLAN 2023/2726 Rev.2.

mitigation measures to be identified by industry. The draft Regulation setting maximum levels of MOAH in food also proposes the alternative options of either applying LOQs to a wide range of food groups considered to be sources of exposure *or* to all foods other than unprocessed products.<sup>15</sup>

More recently, DG SANTE circulated a Working Document<sup>16</sup> to stakeholders proposing to amend Regulation (EU) No 231/2012 laying down specifications for food additives ('the Food Additives Specification Regulation') in order to establish a single legislative maximum level for MOAH applicable to all food additives of 2 mg/kg.

To the author's knowledge, at the time of writing, no specific amendments to EU food contact material legislation concerning MOAH maximum levels had yet been proposed by the Commission.

## II. Current Enforcement

Pending any future adoption of EU legislation establishing maximum levels of MOAH in food, any mandatory withdrawal or recall from the EU market of foods in which a quantified presence of MOAH is

identified will be on the basis of the (non-legally binding) Joint Statement.

At the April 21 2022 SCoPAFF meeting, the Commission stated that the Joint Statement was 'applicable as from the moment the minutes of the SCoPAFF meeting of 21 April 2022 are published'. In practice, however, enforcement of the LOQs by relevant EU Member State authorities has varied in terms of both timing and scope. For example, the Spanish Food and Nutrition Agency previously noted that EU Member States would take appropriate risk management measures only 'once...[EFSA's updated risk assessment was] published'.<sup>17</sup> In a similar vein, the Netherlands Food and Consumer Product Safety Authority previously announced a temporary enforcement policy for MOAH in food commencing only on 1 January 2024 which confirmed that it would not generally require withdrawal from the market of food (other than infant formula and its variants) with a fat content >50% meeting or exceeding the 2 mg/kg LOQ stipulated in the Joint Statement.<sup>18</sup>

Meanwhile, it can be expected that downstream final food producers concerned to avoid any withdrawal or recall of their products meeting or exceeding the LOQs defined in the Joint Statement will seek assurances (and potentially contractual indemnities) from their upstream ingredient suppliers regarding MOAH levels in their supplied products.

Certain EU Member State enforcement authorities have also made clear that they expect FBOs to include control of MOAH levels in their plans based on the Hazard Analysis and Critical Control Point ('HACCP') principles<sup>19</sup> and that this will be the subject of enforcement investigations.

## III. Legal Basis?

Some important questions arise regarding the legal basis for any mandatory withdrawal or recall of a food pursuant either to the Joint Statement or to any future EU legislation establishing maximum MOAH levels in food.

The risk management measures proposed in the Joint Statement, which describes MOAH as 'possible genotoxic carcinogens', appear to be based on the precautionary principle. EFSA's updated risk assessment confirmed, on the basis of an incomplete risk characterisation,<sup>20</sup> that 'genotoxicity and carcino-

15 Option 2 in the Annex to the draft Regulation setting maximum levels of MOAH in food refers to 'All foods other than fresh and frozen fruits and vegetables, fresh and frozen meat and offal of terrestrial animals, fresh and frozen fish and other seafood'.

16 Working Document, Establishment of the maximum limit for MOAH in the food additive specifications.

17 Spanish Agency for Food Safety and Nutrition, Webpage on Mineral Oil Hydrocarbons [https://www.aesan.gob.es/AECOSAN/web/seguridad\\_alimentaria/ampliacion/hidrocarburos\\_aceites\\_minerales.htm](https://www.aesan.gob.es/AECOSAN/web/seguridad_alimentaria/ampliacion/hidrocarburos_aceites_minerales.htm) dated 16 March 2023, Section on 'Risk Management'.

18 Temporary enforcement policy of NVWA (Dutch Food and Safety Authority) for MOAH in food products as of January 1, 2024 Tijdelijk handhavingsbeleid NVWA MOAH in levensmiddelen per 1 januari 2024 <<https://www.nedverbak.nl/uploads/2023/12/tijdelijk-handhavingsbeleid-nvwa-moah-in-levensmiddelen.pdf>> Section 1., p. 1.

19 Tijdelijk handhavingsbeleid NVWA MOAH in levensmiddelen per 1 januari 2024 <<https://www.nedverbak.nl/uploads/2023/12/tijdelijk-handhavingsbeleid-nvwa-moah-in-levensmiddelen.pdf>> pp. 2 and 3: 'When MOAH is found in food products, this may prompt the NVWA to conduct an inspection to verify whether a company is fulfilling its responsibilities regarding raw material control and hazard analysis related to MOAH. If this is not the case, and the NVWA identifies a violation in the area of HACCP, the NVWA will enforce...' (translation from Dutch).

20 EFSA's updated risk assessment, Section 4.3., 95: 'The CONTAM Panel noted that a full risk characterisation would require additional data on toxicity and exposure to three or more ring MOAH'.

genicity are associated with MOAH with three or more aromatic rings.<sup>21</sup> However, in the absence of any risk characterisation being possible for MOAH with one to two aromatic rings, EFSA was able to conclude only that these MOAH ‘might raise a concern’.<sup>22</sup> Yet the withdrawal or recall requirement in the Joint Statement applies to the sum of *all* MOAH concentrations, irrespective of the number of aromatic rings present. In such circumstances, it appears doubtful that the requirement under Regulation (EC) No 178/2002 that risk management measures based on the precautionary principle be adopted only where ‘following an assessment of available information, the possibility of harmful effects on health is identified’<sup>23</sup> has been met concerning MOAH with one or two aromatic rings. Speculation, in the absence of any risk characterisation, that such MOAH ‘might’ be harmful to health does not equate to the specific identification of possible harmful effects on health. Rather, it is difficult to see how any mandatory withdrawal or recall requirement relating to such MOAH could be characterised other than as a precautionary measure ‘based on a purely hypothetical approach to the risk, founded on mere assumptions which have not yet been scientifically verified’ which the Court of Justice of the European Union has previously held to be invalid.<sup>24</sup> This point is particularly relevant in the light of recent studies suggesting that, notwithstanding EFSA’s focus in its updated risk assessment on the risks of MOAH with three or more aromatic rings, the significant majority of MOAH contamination in at least some foods is by MOAH with one to two aromatic rings.<sup>25</sup>

A further issue is whether the risk management measures under the Joint Statement or under any future EU legislation establishing maximum MOAH levels in food are or will be disproportionate and discriminatory in their application. The measures in the Joint Statement are reminiscent of the controversial ‘harmonised’ EU approach previously adopted in relation to ethylene oxide (‘ETO’) contamination, with the important difference that the existing harmonised classification of ETO as carcinogenic 1B, mutagenic 1B and toxic for reproduction 1B under Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances at the time of adoption of that approach arguably justified the ‘zero tolerance’ prohibition of its presence in food above detection limits. Regulation (EC) No 178/2002 requires that measures based on the pre-

cautionary principle ‘shall be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community’<sup>26</sup> and the Commission previously noted both that ‘reliance on the precautionary principle is no excuse for derogating from the general principles of risk management...include[ing] proportionality [and] non-discrimination’ and that ‘the principle of non-discrimination means that...different situations should not be treated in the same way, unless there are objective grounds for doing so. Measures should not be discriminatory in their application’.<sup>27</sup>

A mandatory withdrawal or recall requirement for food products meeting or exceeding the LOQs stipulated in the Joint Statement or exceeding maximum levels for MOAH established under future EU legislation which applies irrespective of the number of aromatic rings of the relevant MOAH concentrations may itself be considered disproportionate and discriminatory. The European Court of Justice has previously found that the blanket, indiscriminate application of a restrictive precautionary risk management measure to an entire group of compounds on

21 EFSA’s updated risk assessment, Abstract, p. 1.

22 EFSA’s updated risk assessment, Section 4.1.5., p. 93: ‘Little is known regarding the toxicity of 1–2 ring MOAH. Overall, the lack of robust data on the oral toxicity of MOAH hampers the possibility to identify the critical effects and a RP related to the non-genotoxic and non-carcinogenic fraction of MOAH’. EFSA’s updated risk assessment, Section 4.3., p. 95: ‘Due to the lack of adequate oral toxicity studies, it was not possible to identify a reference point for the 1–2 ring MOAH. Therefore, a risk characterisation of this MOAH fraction could not be performed. The CONTAM Panel concluded that, in the absence of reliable toxicity data, the dietary exposure to 1–2 ring MOAH might raise a concern’.

23 Article 7(1) of Regulation (EC) No 178/2002.

24 Joined Cases C-58/10 to 68/10, paragraph 77.

25 *Quantification of mineral oil aromatic hydrocarbons by number of aromatic rings via comprehensive two-dimensional gas chromatography: First results in food*, Maurus Biedermann, Angela Eicher, Tanja Altherr, Gregor McCombie, *Journal of Chromatography Open*, Volume 2, November 2022. For example, see pp. 10 and 11: ‘A total of 34 samples of infant formula were analyzed for ≥3 ring MOAH...When samples contained MOAH, they were almost exclusively composed of 1–2 ring MOAH for all samples. Though there are risks associated with all MOAH, the risks posed by ≥3 ring MOAH are considered higher by EFSA, than those with 1–2 rings. These results reduce urgency arising from the amounts of MOAH found in certain infant formula’.

26 Article 7(2) of Regulation (EC) No 178/2002.

27 Section 6.3. and 6.3.2. of the Communication from the Commission on the precautionary principle, Brussels, 2.2.2000 COM(2000) 1 final <<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52000DC0001>>



the basis of a risk assessment covering only certain of those compounds is not permitted.<sup>28</sup>

In addition, the LOQs agreed in the Joint Statement apply to all MOAH (covering the fraction of C10-C50) and foods (subject only to a fat content distinction) without differentiation. This ignores both the fact that MOAH are ‘a diverse group of chemical compounds’<sup>29</sup> and that Regulation (EU) 2023/915 of 25 April 2023 on maximum levels for certain contaminants (‘the Contaminants Regulation’) requires maximum contaminant levels to be set at a level which is as low as reasonably achievable (‘ALARA’) ‘by following good agricultural, fishery and manufacturing practices and taking into account the risk related to the consumption of the food’, both of which factors vary from food to food.<sup>30</sup> The same would be true, *mutatis mutandis*, of any future adoption of a single legislative maximum level for MOAH applicable to all food additives as recently proposed by the Commission. Such indiscriminate application of maximum levels is also contrary to the established legislative practice under both the Contaminants Regulation and the Food Additives Specification Regulation of adopting specific maximum levels for individual MOAH (for example, benzo(a)pyrene and other polycyclic aromatic hydrocarbons).<sup>31</sup> The Commission’s recognition in its draft Regulation setting maximum levels of MOAH in food<sup>32</sup> and related discussion paper<sup>33</sup> that for certain foods MOAH concentrations below the LOQ cannot be achieved on the basis of currently available best practices only serves to highlight this shortcoming in the Joint Statement.<sup>34</sup>

The above issues arise in large part due to the fact that the Joint Statement was agreed by the SCoPAFF prior to EFSA’s updated risk assessment, notwithstanding stakeholder concerns about the wisdom of this at the time,<sup>35</sup> and therefore in advance of gathering the further data referred to in that Opinion as necessary for arriving at a more comprehensive risk assessment of MOAH contamination of food. In the absence of any further EFSA risk assessment in the interim, the same issues look set to plague any future EU legislation establishing maximum MOAH levels.

Finally, precautionary measures must be ‘provisional (...) pending more scientific information for a more comprehensive risk assessment’ and ‘reviewed within a reasonable period of time.’<sup>36</sup> The Commission’s plan to codify the Joint Statement’s LOQs (at least for most foods) in a Regulation setting maximum levels of MOAH in food, with no review clause (according to the current draft) and potentially prior to any further EFSA risk assessment, does not appear to be consistent with this requirement.

#### IV. Analytical Methods

Both the European Commission and EFSA have recently recognised that analytical methods for MOAH require further development.

In its updated risk assessment, EFSA noted that the current analytical method for determining MOAH concentrations in food and food contact ma-

28 Case C-282/15, paragraphs 64 and 65: ‘the scheme laid down...covers, indiscriminately,...all amino acids and their derivatives, without distinguishing possible categories or types of substances...[T]he risk analysis ...must still clearly identify the common elements or characteristics of the substances concerned, whose real risk for human health cannot be excluded ...[T]he risk analysis and the resulting application of the precautionary principle appear to concern only certain amino acids, which would be insufficient to justify a [restriction]...which applies without distinction to all amino acids’.

29 Commission Europa Webpage on Mineral Oil Hydrocarbons <[https://food.ec.europa.eu/safety/chemical-safety/contaminants/catalogue\\_en](https://food.ec.europa.eu/safety/chemical-safety/contaminants/catalogue_en)>.

30 Recital (2) of Regulation (EU) 2023/915: ‘Maximum levels should be set at a strict level, which is reasonably achievable by following good agricultural, fishery and manufacturing practices and taking into account the risk related to the consumption of the food. In the case of a possible health risk, maximum levels for contaminants should be set at a level, which is as low as reasonably achievable (ALARA)’.

31 See Article 2(1) and Part 5.1 of Annex I of the Contaminants Regulation and the purity criteria for benzo(a) pyrene established for the food additives E 153 (vegetable carbon) and E 905 (micro-crystalline wax) under the Food Additives Specification Regulation.

32 Recital (8) of the Contaminants Regulation: ‘...taking into account the “As Low As Reasonably Achievable Principle” maximum levels for MOAH in food should be set at the limit of quantification. Only for foods, for which it has been demonstrated that, according to the currently best available practices, no concentrations below the limit of quantification can be achieved, maximum levels above this limit should be established’.

33 Page 2 of Commission Discussion paper as regards maximum levels for MOAH in food: ‘General approach for establishing MLs ... It is proposed to establish the MLs at the same levels as the LOQ limits from the statement of the SC PAFF of 21 April 2022, with an exception for higher MLs for certain specific foods, in case it can be demonstrated that, by following good practices, concentrations of MOAH below the LOQ cannot be achieved.’

34 The draft Regulation still applies indiscriminately to all MOAH (covering the fraction of C10-C50), however.

35 Summary Report of 21 April 2022 SCoPAFF meeting: ‘The Commission informed the Member States on stakeholder comments in favour of waiting for the updated EFSA risk assessment before taking further risk management measures’.

36 Article 7 of Regulation (EC) No 178/2002.

terials (on-line coupled liquid chromatography-gas chromatography with flame ionisation detection ('LC-GC-FID')) is 'insensitive and non-specific' insofar as it does not permit identification of the number of aromatic rings and therefore a differentiated exposure assessment between MOAH with one or two aromatic rings and MOAH with three to seven aromatic rings.<sup>37</sup> However, EFSA noted that this is possible using the comprehensive two-dimensional GC (GC × GC) method. EFSA therefore recommended that 'more selective and sensitive analytical method should be implemented' to enable sources of contamination to be investigated when MOAH are detected.<sup>38</sup>

In its discussion paper as regards a monitoring recommendation on MOH in food, circulated late in 2023, the Commission, in light of EFSA's comments, proposed recommending 'further improvement of the analytical methods and analytical capability for MOAH in food' and in particular 'validation of more sensitive analytical methods [based on two dimensional GC], in order to achieve the target LOQs for...MOAH, which are included in the JRC guidance.' However, the draft Commission Implementing Regulation amending Regulation (EC) No 333/2007 as regards the methods of sampling and analysis for the control of levels of MOH in foodstuffs, which was circulated by the Commission at the same time as its monitoring recommendation discussion paper, merely stipulates a set of preventive measure to avoid MOH cross-contamination of samples and cross-refers to the updated JRC Guidance.

In the absence of validated analytical methods for MOAH of sufficient sensitivity, the harmonised enforcement approach based on the LOQs in the Joint Statement contradicts the Commission's recent Guidelines for harmonised risk management approaches and enforcement action in cases of incidents involving food products containing genotoxic carcinogens.<sup>39</sup> These Guidelines specifically state that in such circumstances an approach based on LOQs cannot be used and would only be appropriate in a subsequent phase once sufficient analytical methods have been developed and further information on the relevant contaminant's properties and ways of entering the food chain are available.<sup>40</sup>

The lack of sufficiently sensitive analytical methods also raises obvious questions concerning both the reliability and the relevance to health risks of any confirmation of the quantified presence of MOAH in

food products by official or FBO own controls undertaken today in accordance with the Joint Statement, an issue already recognised at the time of the 19 October 2022 SCoPAFF meeting,<sup>41</sup> and whether the resulting mandatory withdrawal or recall is therefore legally or scientifically justified. This is particularly poignant given the considerable disruption of global supply chains in relation to a wide range of food products which enforcement of the mandatory withdrawal or recall requirement will likely cause.

In that connection, FBOs should consider challenging any official control finding of a quantifiable presence of MOAH in their food products on the basis of the reliability of the analytical method used and should in such circumstances insist on their specific legal right to demand a second expert opinion in relation to any sampling, analysis, testing or diagnosis of their products.<sup>42</sup>

## V. Anticipated Timetable for Adoption of EU Legislation Setting Maximum MOAH Limits in Food

The Commission foresees a relatively tight timetable for adoption of both the final Regulation setting maximum levels of MOAH in food and the anticipated

37 EFSA's 2023 updated risk assessment, Section 1.3.3., p. 16.

38 EFSA's 2023 updated risk assessment, Section 5., p. 96.

39 Ref. Ares(2023)6612068 – 29/09/23 <[https://food.ec.europa.eu/document/download/cf2f5103-20e7-4fea-92d5-82ade0606de1\\_en?filename=pesticides\\_mrl\\_enforcement\\_guidelines\\_genotoxic-carcinogens-incident.pdf](https://food.ec.europa.eu/document/download/cf2f5103-20e7-4fea-92d5-82ade0606de1_en?filename=pesticides_mrl_enforcement_guidelines_genotoxic-carcinogens-incident.pdf)>.

40 See the Section of the Guidelines entitled 'Situations in which the approaches (I) and (II) should be used and legal considerations', p. 7: '*In the starting phase of a new emerging food incident, if there is limited knowledge/data and lack of validated analytical methods with sufficient sensitivity and lack of sufficient laboratory capacity, an approach based on quantification could not be used and the traceability approach would be the only choice to protect consumers. The situation would however be expected to evolve over time: with efforts made by the EU Reference Laboratories to provide the necessary analytical methods, a gradually better understanding of the substance's properties and its way of entry into the food chain, moving to an approach based on quantification should then be considered in the second phase of incident management as a more proportionate risk management option.*'

41 Summary report of the 19 October 2022 SCoPAFF meeting, sante.g.3(2022)8681453: '*A Member State informed that food business operators expressed concerns on how the statement will be implemented by Member States in advance of...the reliability of the analytical methods.*'

42 Article 35 of Regulation (EU) 2017/625 on official controls and other official activities performed to ensure the application of food and feed law.

amendment of the Food Additive Specification Regulation establishing a maximum level of MOAH of 2.0 mg/kg for all food additives.

In a recent stakeholder meeting hosted by the Commission<sup>43</sup> concerning the draft Regulation setting maximum levels of MOAH in food, the Commission requested that industry submit by 27 February 2024 data on occurrence of MOHs in food when using best available practices, information on sources of contamination and available mitigation measures and achievable timelines for avoiding contamination in the near future. The Commission anticipated that the SCoPAFF would vote on the draft Regulation in the third or fourth quarter of 2024, meaning that legislation could be adopted as soon as late 2024 or early 2025. The draft Regulation specifically notes in its Recitals that there should be ‘no transitional period... for products with a long shelf life..lawfully placed on the market before the date of application of the Regulation’ on the basis that EU Member States have already been enforcing MOAH controls for some time.<sup>44</sup> This ignores the perspective of third country (non-EU) suppliers who may be unaware of the Joint Statement or the related withdrawal or recall requirement (which, in contrast to draft legislation, have not been notified at WTO level) as well as the reality that enforcement approaches and their timing have varied in individual EU Member States.

DG SANTE has made clear that it anticipates the amendment of the Food Additives Specification Regulation to follow the same time lines as the draft Regulation setting maximum levels of MOAH in food.<sup>45</sup> ‘Targeted stakeholders’ were invited to comment on the relevant Commission Working Document by 15 March 2024 and to provide supporting data concerning, *inter alia*, any reasons why the proposed 2 mg/kg maximum limit cannot be achieved in relation to specific additives, mitigation measures to reduce MOAH levels, a proposed timeline for complying with the

proposed maximum levels and occurrence data and the LOQ for food additive samples produced according to good manufacturing practices.

## VI. Conclusions

Enforcement of the mandatory withdrawal or recall requirement for food products meeting or exceeding the MOAH LOQs stipulated in the Joint Statement or exceeding MOAH maximum levels established under any future EU legislation will likely lead to significant business interruption of global supply chains for a wide range of food products. Yet both the scientific and legal basis for the harmonised EU enforcement approach to MOAH contamination of food agreed upon to date remains questionable. The introduction of such broadly applicable and non-discriminate risk management measures is premature from a scientific perspective, given the conclusions of EFSA’s updated risk assessment (adopted more than a year after the Joint Statement), its recommendation that crucial data to assess MOAH risks still needs to be gathered, the current lack of sufficiently specific analytical methods as recently recognised by both EFSA and the Commission and the fact that adoption of LOQs in such circumstances contradicts the Commission’s own guidance. In addition, the agreed harmonised enforcement approach has run roughshod over established legal requirements relating to adoption of precautionary risk management measures. These include the requirement to identify by a risk assessment (even if incomplete) the possibility of harmful effects to health of all MOAH compounds subject to risk management measures (including MOAH with one or two aromatic rings) and that such measures be proportionate, non-discriminatory and provisional pending the availability of further scientific information for a more comprehensive risk assessment.

A comparison with the Commission’s more measured and targeted approach to managing the risks of another group of widespread and insufficiently characterised contaminant compounds – Perfluoroalkylated substances (PFASs) – prompts the question why a similar pathway was not taken in relation to MOAH. Rather than introducing maximum levels applicable to all PFASs in all foods (the approach for MOAH under the Joint Statement), maximum levels have to date been established by Commission Regu-

43 Online Forum on Mineral Oil Hydrocarbons (MOHs) in Food, 18 January 2024.

44 Recital (9): ‘Taking into account the fact that Member States have been enforcing controls of MOAH on the basis of Article 14 of Regulation (EC) No 178/2002 in infant and follow on formulae since June 2020 and in all foods since February 2022, and taking into account the fact certain MOAH are genotoxic carcinogens, no transitional measures should be foreseen for products with a long shelf life that were lawfully placed on the market before the date of application of this Regulation.’

45 Working Document, Establishment of the maximum limit for MOAH in the food additive specifications, p. 3.

lation (EU) 2022/2388<sup>46</sup> only in relation to the four PFASs (PFOS, PFOA, PFNA and PFHxS) so far identified as principally responsible for human exposure and these apply only to those foods considered to contribute most to PFAS exposure. This followed a number of previous EFSA Opinions adopted over a sustained period leading to the collection of necessary occurrence data regarding the contribution of foods to human exposure.<sup>47</sup> The Commission has also adopted Recommendation (EU) 2022/1431 on the monitoring of PFASs in food to gather occurrence data ‘in order to support a dietary exposure assessment and assess the need to regulate these substances in specific commodities’<sup>48</sup> including in processed foods. Instead of introducing a mandatory withdrawal or recall requirement for these additional foods in advance of such occurrence data being obtained (the

MOAH approach), the Recommendation rather establishes ‘*indicative levels*’ of concentrations of PFOS, PFOA, PFNA and PFHxS in four additional foods which, when exceeded, should trigger follow-up investigations regarding the source of contamination but which do not prevent placing on the market of the relevant food item.<sup>49</sup> The same Recommendation also adopts a more pragmatic approach to available analytical methods. ‘*Target*’ LOQs are recommended to ‘*encourage*’ the use of sufficiently sensitive analytical methods,<sup>50</sup> whilst at the same it is recognised that ‘Member States which use methods which cannot achieve these limits of quantification may submit results obtained with methods with higher limits of quantification [but] should take the necessary action to achieve the target limits of quantification as soon as possible’.<sup>51</sup>

46 Commission Regulation (EU) 2022/2388 amending Regulation (EC) No 1881/2006 as regards maximum levels of perfluoroalkyl substances in certain foodstuffs (since implicitly repealed and replaced by the Contaminants Regulation).

47 Perfluorooctane sulfonate (PFOS), perfluorooctanoic acid (PFOA) and their salts, Scientific Opinion of the Panel on Contaminants in the Food chain (Question No EFSA-Q-2004-163), adopted on 21 February 2008, The EFSA Journal (2008) 653, 1-131; EFSA Opinion on risk to human health related to the presence of perfluorooctane sulfonic acid and perfluorooctanoic acid in food, adopted 22 March 2018, doi: 10.2903/j.efsa.2018.5194; EFSA Opinion on risk to human health related to the presence of perfluoroalkyl substances in food, adopted 9 July 2020, doi: 10.2903/j.efsa.2020.6223.

48 Recital (6) of Recommendation (EU) 2022/1431 on the monitoring of PFASs in food: ‘In light of the opinion by the Authority,

occurrence data for a wide range of PFASs should be gathered in foods which are relevant for the human exposure to PFASs in order to support a dietary exposure assessment and assess the need to regulate these substances in specific commodities. To this end, specific foods from specific production types or with specific characteristics, for which data are lacking, should be monitored and an estimate of the processing factors for various processed products provided’.

49 Recital (7) and Recommendation 7 of Recommendation (EU) 2022/1431 on the monitoring of PFASs in food.

50 Recital (7) of Recommendation (EU) 2022/1431 on the monitoring of PFASs in food.

51 Recommendation 6 of Recommendation (EU) 2022/1431 on the monitoring of PFASs in food.