GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3S

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Letter to EC June 2025

To Mrs. Veerle Vanheusden

European Commission DG SANTE - Unit E2 – Food processing technologies and novel foods

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Dear Mrs. Vanheusden,

GOED, the Global Organization for EPA and DHA Omega-3s (https://goedomega3.com/), represents the worldwide EPA and DHA omega-3 industry, with a mission to use science-based information to promote the consumption of and enable access to quality EPA & DHA from all sources for a positive impact on public health. The membership is built on a voluntary industry standard and ethics guidelines, with which our members must comply to ensure that they produce quality products that consumers can trust. Our 220+ members (link) represent the entire global supply chain of EPA and DHA omega-3s, from fisheries and crude oil suppliers to refiners, concentrators and finished product brands. About 35% of our members are companies based in the EU and European Economic Area.

GOED has learned that the European Commission has issued several documents with proposals that aim to regulate mineral oil hydrocarbons (MOHs), including:

1. SANTE PLAN 2023/2345 Rev.7: Commission Regulation (EU) amending Regulation (EU) 2013/915 as regards maximum levels of mineral oil aromatic hydrocarbons in food, and the associated Annex

2. SANTE PLAN 2023-2727 Rev.5: Commission Recommendation on the monitoring of mineral oil hydrocarbons in food

3. SANTE PLAN 2023 2726 Rev.6: Commission Implementing Regulation (EU) amending Regulation (EC) No 333/2007 as regards the methods of sampling and analysis for the control of levels of mineral oil hydrocarbons in foodstuffs, and the associated Annex.

GOED would like to express its appreciation for the work the EC is doing to regulate MOSH and MOAH in foods. We recognize the challenges in regulating extraordinarily complex mixtures of substances that

can potentially contaminate food and we are pleased to see how the draft regulation has evolved since we last communicated on the topic (see attached letter dated 22 February 2024).

Despite the absence of a current public consultation, we would like to provide feedback on your proposals given their relevance to our sector, where a large proportion of the ingredient oils originate from outside the EU, both as crude (unrefined) and as refined EPA/DHA omega-3 oils. GOED members are well aware of the need to prepare for the upcoming regulation and have made the necessary adaptations where feasible and achievable to minimize the levels of MOSH and MOAH in their products. Nevertheless, as detailed below, there are some outstanding points of uncertainty in the latest proposal for which we seek clarification, and we would like to make specific suggestions that are relevant to our sector.

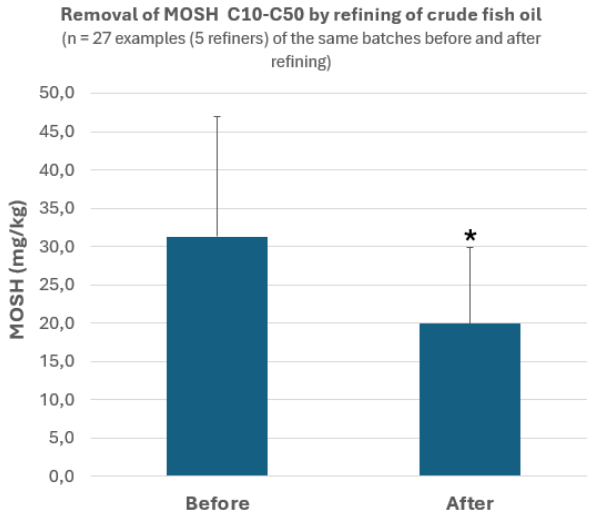
1. GOED recommends reinstating the category name as "Fish Oils and Oils from Other Marine Organisms, and Algae"

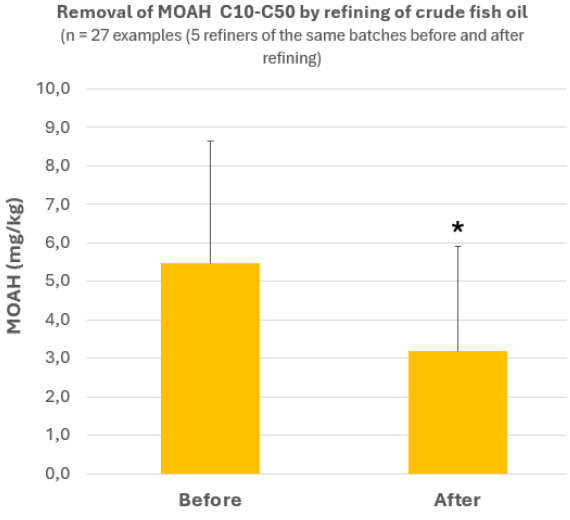
The current category description of EPA/DHA omega-3 oils in Section 5.5.2.5 "Oils produced from fishery products and algae" has changed from "Fish Oils and Oils from Other Marine Organisms, and Algae" used in previous document versions and other contaminants regulations by the EC. GOED suggests using the preferred and more comprehensive original wording, which would cover all the sources that are relevant to our sector. It is unclear if the term "fishery products" also encompasses marine sources of EPA/DHA omega-3 oils such as, for example, krill, squid and calanus, which do not originate from fish. It would furthermore be more accurate to use the word "microalga" instead of "algae," since macroalgae are not used to produce edible oils, as far as we know. If the EC decides to maintain the term "fishery products" in the regulation, it needs to be clearly defined.

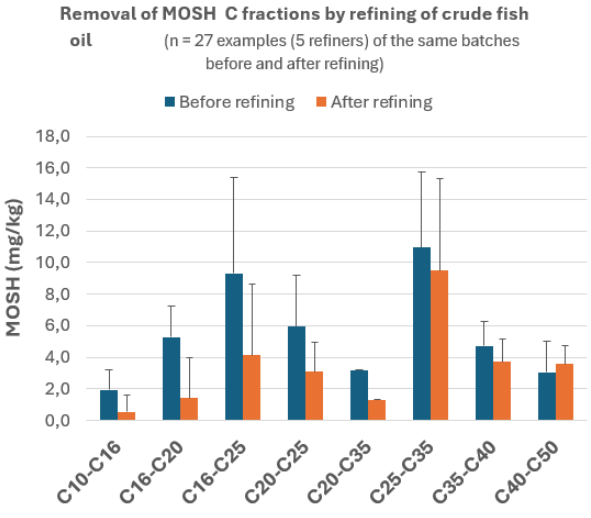
2. GOED recommends setting a customized higher Maximum Level for crude unrefined EPA/DHA omega-3 oils because these oils will be refined prior to consumption

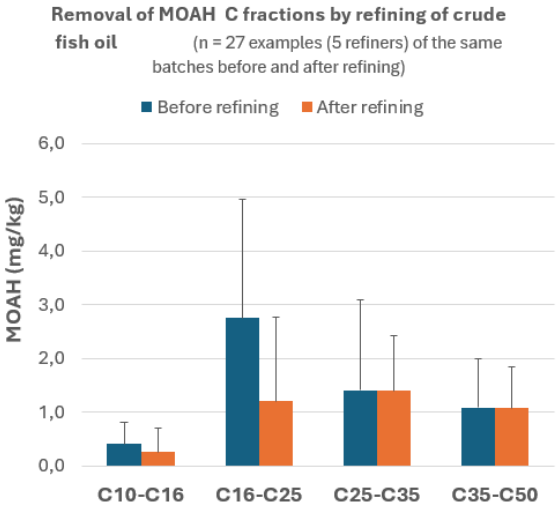
It is not clear if crude unrefined EPA/DHA omega-3 oils are currently within the scope of Section 5.5.2.5 - "Oils from Fishery Products and Algae," (with a proposed ML of 10 mg/kg from 1 January 2027, and 5 mg/kg from 1 January 2030). Fish oil refining is performed to make fish oils suitable for human consumption, which includes reducing contaminants to levels compliant with EU regulations for finished omega-3 oils. Refining in general comprises gum conditioning, neutralization, washing, drying, bleaching, filtration, and deodorization or short path distillation. The principal aim of the refining process is the removal of undesirable taste and odor and the removal of environmental pollutants, such as dibenzo-*p*-dioxins, dibenzofurans, dioxin-like polychlorinated biphenyls, and non-dioxin-like PCBs. The implementation of MLs for MOAH applicable from 2027 onward will, by default, compel all market actors to ensure their finished omega-3 oils comply with these limits.

In this context, it is preferable not to apply MLs for MOSH and MOAH to crude unrefined omega-3 oils equivalent to those set for refined oils, as these crude oils are not intended for direct human consumption. Fish oil refining is where partial mitigation of both MOSH and MOAH can be achieved, with examples shown in the following graphs:







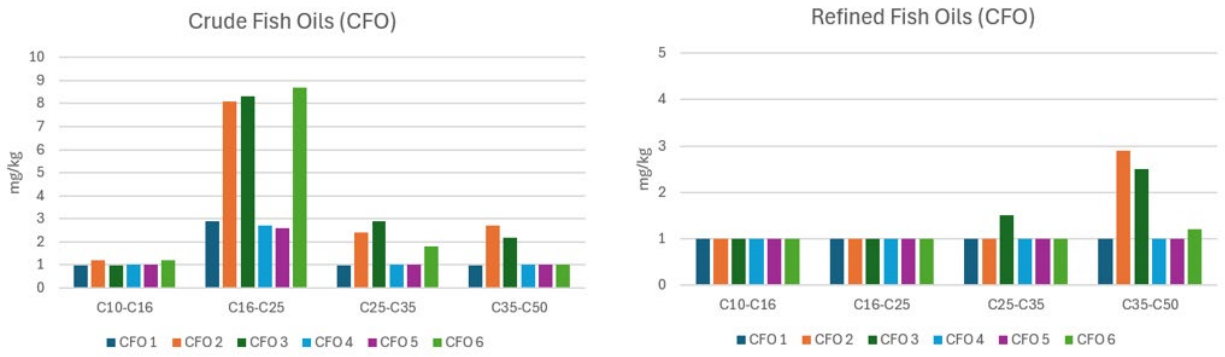


The graphs show that fish oil refining achieves about 50% reduction on average in apparent MOSH and MOAH levels. The removal of both MOSH and MOAH by refining is limited to the shorter chain

compounds, up to about C25. Heavy weight MOH (> 25 carbons) are resistant to removal by the standard fish oil refining approaches. Further removal of MOH < 25 carbons, and partial removal of MOH > 25 carbons can be achieved, but at the risk of creating trans-fatty acids and 3-MCPD/glycidyl esters that would exceed EU regulations for these process contaminants. Of note, during refining some of the natural components you find in crude unrefined omega-3 oils that interfere with the MOSH and MOAH analysis are also removed.

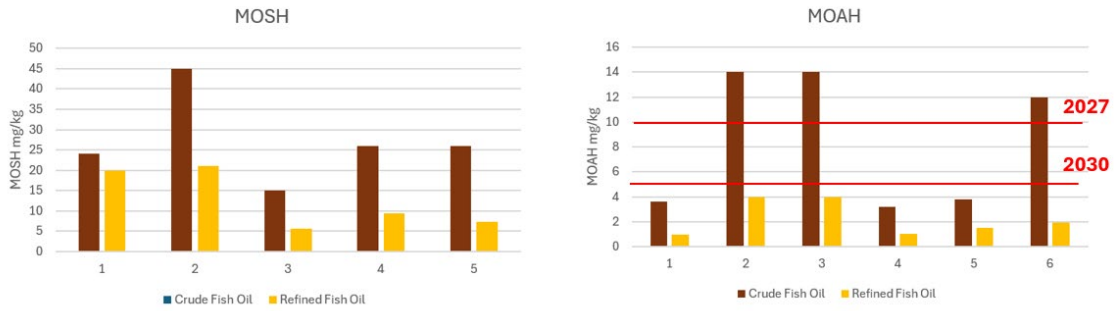
Taking into consideration the above reduction in levels achieved by refining, and compounded by the fact that often a portion of the signal is not MOAH (see Point 6 below), an ML is not warranted for crude unrefined omega-3 oils. However, if an ML must be set, we recommend an ML of **15 mg/kg** for crude unrefined EPA/DHA oils that are destined to be refined (which an estimated 92% of crude unrefined omega-3 oils will meet). This would allow compliance and further mitigation by using refining to meet the proposed MLs of 10 mg (2027) and 5 mg/kg (2030) by the omega-3 sector. This would also be aligned with the existing EU regulation for polycyclic aromatic hydrocarbons (PAH), which have a similar chemical nature to MOAH. The PAH regulation sets an ML for finished products and the ingredient oil used for finished products, but not for crude unrefined oils. Maintaining the proposed MLs only for refined, finished omega-3 oils, while setting a higher ML for crude unrefined EPA/DHA omega-3 oils that are destined to be refined, would leave room for process optimization and innovation within the supply chain.

An example of currently ongoing innovation in the refining process for fish oils is molecular distillation/short path distillation (SPD), which is used, for example, to reduce the PCB content of fish oil. This makes this technology well suited for decontamination of crude fish oils. Generally, no detrimental effects on the nutritional quality of fish oil can be detected by SPD treatment, and preservation of polyunsaturated fatty acids confirms the gentle conditions under which SPD can operate. In this example from a major fish oil producer, molecular distillation/SPD of crude fish oils effectively removes all short-chain MOAH (up to C25):



The long chain hydrocarbons (C35 to C50) are in a similar vapor pressure range as many other valuable components of the oil; therefore, their separation is much more challenging.

In another example, SPD allows a reduction of MOH to levels below the proposed MLs for refined oils even when applied to crude unrefined fish oils that exceed the proposed limits:



These examples show that mitigation of apparent MOSH and MOAH by refining, and further innovations in refining, are absolutely necessary in our sector, and that the application of the same limits for both crude unrefined oils and refined oils is not appropriate for our fish oil producers.

3. GOED recommends creating a category for ingredient oil blends of category 5.5.2.5 and vegetable oils

In the omega-3 sector, a significant portion of food supplements are blends of an EPA/DHA omega-3 oil with vegetable oils. While dietary supplements are mentioned in the proposed regulation (category 5.5.12), ingredient oils that are blends of oils of different origins are not covered explicitly in any of the categories of SANTE PLAN 2023/2345 Rev.7. We would like to suggest that a category is created for the corresponding ingredient oil blends of an oil from category 5.5.2.5 and any vegetable oil falling under section 5.5.2., with an ML corresponding to the category that comprises the major part of the ingredient oil blend.

4. GOED recommends including the handling of measurement uncertainty in SANTE PLAN 2023 2726 Rev.6

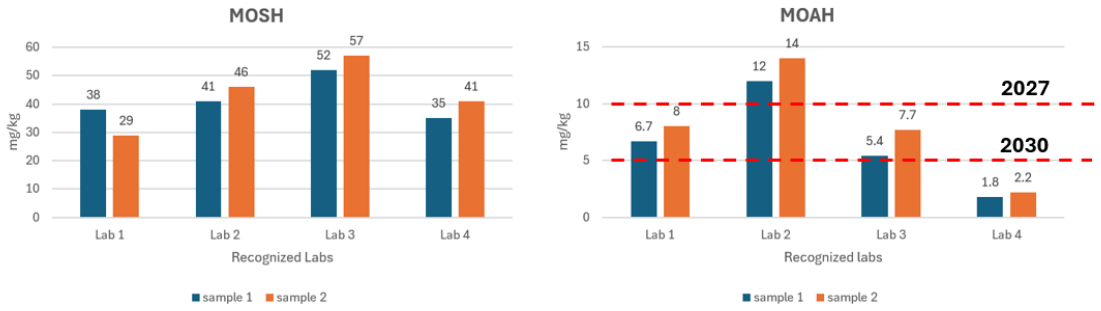
In SANTE PLAN 2023 2726 Rev.6, there is no mention of the proposed practice for handling measurement uncertainty in the determination of the reported value of a measured MOSH or MOAH level. This should include the possibility that FBOs subtract the measurement uncertainty from the measured value to determine the value they can report on their product certificates. This is critical for our members to decide whether their oil is suitable to be marketed in the EU, especially when the ML of 5 mg/kg enters into force in January 2030. It is possible that this will be automatically applied when

Regulation EC 333/2007 is amended by including MOH, but since this is so important for our sector, we would like to have this confirmed in writing.

5. GOED recommends European Commission guidance on the need for organizing a laboratory proficiency program for EPA/DHA omega-3 oils

The variability in MOSH/MOAH testing results between the different commercial third-party laboratories remains very high, and no convergence between testing results has been observed since we addressed this in our letter last year. Without a laboratory proficiency program in which omega-3 oils spiked with known amounts of MOSH and MOAH are included as test samples, companies do not know which commercial laboratories can quantify MOH accurately.

For example, a recent ring test carried out by one of our member producers assessed the results obtained for two different crude unrefined fish oil samples analyzed by four different third-party laboratories in Europe.



The results show that the interlaboratory variability is still very large today. It also shows that, depending on the laboratory, the same sample will either be classified as compliant with MLs proposed to be implemented in 2027 and/or 2030, or not at all. It is impossible to conclude which commercial laboratory is correct in its assessment today. A regulation based on a method that cannot be carried out reproducibly by commercial laboratories cannot reliably be put into practice.

Discussions with the director of the EU Reference Laboratory for Processing Contaminants in Denmark have made clear to us that EPA/DHA omega-3 oils are not a priority to be included in the proficiency programs organized occasionally by the EC to determine the proficiency of participating official and commercial laboratories. The current lack of guidance on this point is also leading to circumstances where FBOs choose to work with the third-party laboratory that gives them the lowest results (which may not be accurate). The methods (i.e. EN 16955 and ISO 20122) recommended by the EC were originally developed for clean vegetable oils that, unlike marine oils, do not suffer from significant matrix interference. While we appreciate the ML for category 5.5.2.5 being proposed at 10 mg/kg, with which

our sector can comply, and the LOQ now being raised to 5,0 mg/kg, which considers the presence of background natural interference, the analytical methods are not fit-for-purpose in general. A laboratory proficiency program will inform our members which laboratory is actually accurate and also make laboratories accountable for improving their accuracy over time.

6. GOED recommends recognition of limitations and rising analytical testing costs for confirmatory analyses of EPA/DHA Omega-3 Oils because of the need to deal with inevitable matrix interference

Lastly, and as a point of information for the Commission, we are pleased that specific language was included in the latest documents recognizing the presence of interfering substances in the analytical testing of MOSH and MOAH in certain commodities, including EPA/DHA omega-3 oils (Fish Oils and Oils from Other Marine Organisms, and Algae). GOED member companies have long suspected and observed the presence of natural (biogenic) interferences in EPA/DHA omega-3 oils that behave as MOSH or MOAH in the analytical methods EN 16955 2017 and ISO 20122 2024, which leads to false-positive results. When interferences are dominant over a genuine MOAH contamination, the proposed regulation for MOH is basically gauging the ability of companies to keep these analytical interferences below the proposed ML of 10,0 mg/kg, which is an unintended consequence of the choice of methodological approach to quantify all MOSH and MOAH together without any compound identification.

Regulation (EC) No. 333/2007 of March 28, 2007 states in section C.3.3.1 regarding the specific operating criteria of analytical methods that when there are no specific methods for the determination of contaminants, laboratories may choose any method, but it must be validated for the corresponding matrix. This is relevant because currently there is no official method for reliably quantifying MOH developed for crude or refined marine oils (fish and others) which can contain significant levels of interfering compounds. While some third-party laboratories may validate a method for a specific type of fish oil, there is no official method for the quantification of MOSH/MOAH in omega-3 EPA/DHA oils as a category.

Additionally, the JRC Guide for sampling, analysis and reporting of data for monitoring mineral hydrocarbons (2023), which provides the essential performance requirements for the methods to be applied in MOH analysis (point 4.6 of the document), states that the final analytical procedure should undergo validation to prove its fitness for purpose. We believe that fitness for purpose has not been satisfactorily achieved yet for EPA/DHA omega-3 oils, which suffer significant matrix interference that is very different from other edible oils, and which is illustrated by the high interlaboratory variability.

The recommended confirmatory analyses with GC x GC-TOF-MS and GC x GC-TOF-MS/FID, which are slowly becoming available from third-party laboratories, can assist in confirming the presence of such interferences and allow the parallel quantification of MOSH and MOAH, but only if there is not too much interference overlapping with the authentic MOH signals.

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Furthermore, group standards for MOSH and MOAH for the confirmatory analyses are currently non-existent, and quantification relies on group means of proficiency testing exercises, which in addition do not include omega-3 oil matrices. This will keep the accurate quantification of MOSH and MOAH by confirmatory analyses out of reach for the near future until adequate group standards become available for bidimensional confirmatory analyses.

Our sector would like to receive your guidance on these points.

We would appreciate it if you could confirm receipt of this letter,

With kind regards,

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