



GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3S

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To: Mr. Jiří Sochor & Mrs. Veerle Vanheusden,

European Commission
DG SANTE - Unit E2 – Food processing technologies and novel foods
Rue Breydel 232
Office B232- 4/45
B-1049 Brussels/Belgium
+32 2 299 06 12
jiri.sochor@ec.europa.eu / veerle.vanheusden@ec.europa.eu

Statement on proposed legislation for establishing maximum limit for MOAH for the food additive mixed tocopherols

Dear Mr. Jiří Sochor and Mrs. Vanheusden,

This letter has been prepared by [GOED](#), the Global Organization for EPA and DHA Omega-3s. GOED is an international trade association representing the global eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) omega-3 industry. Our 200+ [members and partners](#) represent the entire supply chain of EPA and DHA omega-3s, from oil producers to refiners, concentrators, contract manufacturers and finished product brands. About 25 percent of our members are European companies, and many other members produce ingredients and finished products that are marketed in the EU. Products produced by our members encompass food supplements (including the ingredient oils for these), DHA-rich oils for use as an ingredient in infant formula, EPA/DHA-rich oils for use as an ingredient in functional foods, and EPA- and EPA/DHA-rich oils for use as active pharmaceutical ingredients (APIs) in pharmaceutical omega-3 products. To retard oxidation of EPA/DHA-rich oils, our members use food additives (e.g. mixed tocopherols). For this reason, GOED members have taken an interest in the European Commission's (EC) work on establishing maximum limits (ML) for mineral oil aromatic hydrocarbons (MOAH) in food additives and would like to provide some comments for your consideration.

Our main points are as follows:

- At this time, due to interference, the concentration of MOAH cannot be measured in mixed tocopherols. If the ML is approved, these antioxidant products, which are indispensable for use in the EPA/DHA omega-3 industry, will no longer be able to be imported or made available for use by our European members.
- Before setting maximum levels on MOAH, a suitable method must be developed for analyzing MOAH in mixed tocopherols (vegetable oil-based mixed tocopherols). Current analytical options do not provide satisfactory and reliable results.



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Background:

Final concentrations of mixed tocopherols (E306) in bulk refined oils and in finished omega-3 oil products for sale to consumers typically range from 0.1 to 0.5% (w/w). Mixed tocopherols are usually vegetable oil-based products, with the tocopherols concentrated and dissolved in oils such as sunflower or soybean oil. Mixed tocopherols are the primary antioxidant used by the EPA/DHA omega-3 industry to control oxidative quality during oil refining and processing, storage and finished product formulation. Many companies in the omega-3 supply chain purchase and use mixed tocopherols for their products. This is of particular relevance to our European members who would no longer be able to purchase and use mixed tocopherols if any ML for MOAH would be implemented for this food additive, for the following reason.

A significant matrix interference is frequently observed in mixed tocopherol products when recommended methods for the quantification of MOAH are used (EN 16995 2017 and/or DGF-C-VI 22 (20)). In fact, one third-party laboratory has recently started to inform clients submitting fish oils and omega-3 concentrates for quantification of MOAH that oils with tocopherol levels > 0.2% leads to interference and cannot be analyzed. Due to the presence of natural interferences, the limit of quantification (LOQ) frequently needs to be raised to values well above the proposed 2 mg/kg ML, precluding the determination of the concentration of MOAH in mixed tocopherols. A few examples showing that matrix interference leads to LOQs in the range of 100 to 150 mg/kg are provided in the **Appendix** of this letter.

Furthermore, identification of interferences and quantification of MOAH via two-dimensional gas chromatography (when possible) as a confirmatory test poses financial challenges and may not consistently yield conclusive results due to the lack of a comprehensive library of reference data for the interferences.

It is also worth mentioning that any contamination of mixed tocopherols with MOAH would have a negligible effect on the final MOAH level, since the dilution used when added to an omega-3 oil is in the order of 200x-1000x.

We hope that the EC appreciates our observations and bringing this to your attention,

Respectfully,

Gerard Bannenberg, Ph.D.
Director, Technical Compliance &
Outreach
gerard@goedomega3.com

Harry B. Rice, PhD
Vice-President, Regulatory
& Scientific Affairs
harry@goedomega3.com



Appendix

Table 1. Quantification of MOAH in a mixed tocopherol product (sunflower oil-based)

Mixed tocopherol product	MOAH C10-16 mg/kg	MOAH C16-25 mg/kg	MOAH C25-35 mg/kg	MOAH C35-50 mg/kg	MOAH C10-50 mg/kg, total integrated
A	< 5	< 50	< 350	< 20	< 400

Interpretation: Significant matrix interference in all MOAH C-fractions, as shown by the need to elevate LOQs to between 5 and 350 mg/kg, with a raised LOQ of 400 mg/kg for the total C10-50 content. Analysis carried out with method DIN EN 16995 2017-08 (mod.).

Table 2. Quantification of MOAH in a mixed tocopherol product (sunflower oil-based)

Mixed tocopherol product	MOAH C10-16 mg/kg	MOAH C16-25 mg/kg	MOAH C25-35 mg/kg	MOAH C35-50 mg/kg	MOAH C10-50 mg/kg, total integrated
B	< 100	< 100	< 100	< 100	< 150

Interpretation: Significant matrix interference in all MOAH C-fractions, as shown by the need to elevate LOQs to 100 mg/kg, with a raised LOQ of 150 mg/kg for the total C10-50 content.

Table 3. Quantification of MOAH in a mixed tocopherol product (sunflower oil-based)

Mixed tocopherol product	MOAH C10-16 mg/kg	MOAH C16-25 mg/kg	MOAH C25-35 mg/kg	MOAH C35-50 mg/kg	MOAH C10-50 mg/kg, total integrated
C	< 100	< 100	< 100	< 100	< 100

Interpretation: Significant matrix interference in all MOAH C-fractions, as shown by the need to elevate LOQs to 100 mg/kg, with a raised LOQ of 100 mg/kg for the total C10-50 content.



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Table 4. Quantification of MOAH in an antioxidant mixture with 10% mixed tocopherols

Mixed tocopherol product	MOAH C10-16 mg/kg	MOAH C16-25 mg/kg	MOAH C25-35 mg/kg	MOAH C35-50 mg/kg	MOAH C10-50 mg/kg, total integrated
D	< 100	< 100	< 100	< 100	< 100

Interpretation: Significant matrix interference in all MOAH C-fractions, as shown by the need to elevate LOQs to 100 mg/kg, with a raised LOQ of 100 mg/kg for the total C10-50 content.