



GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3S

Global Organization for EPA and DHA Omega-3s (GOED) - Provision of Information on the Levels of 2-MCPD, 3-MCPD, their esters, and Glycidyl esters in EPA/DHA-rich oils (fish body oils, fish liver oils, and concentrates).

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By means of this letter, GOED is providing information on the presence and levels of 2-MCPD, 3-MCPD, their esters, and glycidyl esters in eicosapentaenoic acid (EPA)- and docosahexaenoic acid (DHA)-rich oils that are used for the production of finished products containing EPA and DHA. These oils include refined fish oils, concentrated forms of EPA and DHA, as well as microbial, algae, krill and terrestrial oils rich in EPA or DHA. This letter also provides our thoughts on the elaboration of maximum levels of these contaminants in EPA/DHA-rich oils used as ingredient for finished products.

GOED represents over 200 companies globally active in the omega-3 business, and among its members are the majority of the producers of oils rich in EPA and DHA omega-3 fatty acids, including fish oil, other marine oils and terrestrial oils. In addition, our membership includes the largest finished product manufacturers producing omega-3 supplements globally (See <http://www.goedomega3.com/index.php/our-members/list-of-goed-members> for a list of GOED members). We hereby provide additional input to be taken into consideration at upcoming Expert Meetings with the Member States, with respect to the appropriateness of setting strict maximum levels for glycidyl esters and 3-MCPD esters in food supplements containing EPA and DHA-containing oils, including fish body oils or fish liver oils.

Upon request, several members of GOED that are producers of fish oils, analytical laboratories with experience in the analysis of EPA/DHA-rich oils, and finished product manufacturers that use EPA/DHA-rich oils in their products have provided data on the levels of these process compounds in various types of EPA-/DHA-rich oils. This information is summarized in Table 1 (provided as a separate file), and below under points 1 and 2. It is important to stress that this data reflects only a small part of the oils that our members handle.



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GOED would like to make some general comments on the origin of MCPDs and their esters and glycidyl esters in EPA-/DHA-rich oils. Crude fish oils (the starting material for the fish oil production process) do not show significant levels of MCPDs, their esters or glycidyl-esters. However, analogous to palm oil, these oils have higher amounts of diglycerides, which are precursors for these specific process contaminants. In addition to this, the presence of traces of chlorine (inorganic and organic; derived from sea water) is also obvious for those oils that have a marine origin (fish oils and krill oils). In other words, the starting material for refined EPA/DHA-oil production contains variable amounts of the chemical substrates for MCPD formation, but, depending on the type and intensity of processing, and the degree to which diglyceride and chloride content decreases along the refining process, MCPDs and glycidyl esters are formed to varying degrees.

As part of the manufacturing process, crude fish oils, and EPA-DHA-rich oils originating from other biological sources, are typically processed through distillation and/or deodorization in order to refine the crude oils, and make them suitable for human consumption. Dedicated concentration processes are used to increase the concentrations of EPA and DHA (see accompanying diagram for a general overview of processing steps). Depending on the processing conditions (temperature, time, equipment), higher levels of MCPDs may be created during refining. Balance between the risk for the appearance of process contaminants and the attainment of quality in terms of sensory or other impurities is required by producers of EPA/DHA-containing oils.

No systematically-collected data on formation and levels of these process contaminants is currently available. Although no change in the level of these process contaminants is expected to occur when the oils are used for the manufacturing of finished products, we currently do not have insight in the levels in finished products. It should be kept in mind that if glycidyl-esters and MCPDs are detected in higher than expected levels, other sources and routes of contamination should be considered, for example from other ingredients that may have been used or contamination that may have occurred in the process of finished product manufacturing.

1. Information on the levels of 2-MCPD, 3-MPCD, MPCD-esters and glycidyl-esters in different fish body oils, fish liver oils, and EPA/DHA concentrates.

Information on the levels of 2-MCPD, 3-MPCD, their esters, and glycidyl esters in distinct batches of a range of EPA/DHA-containing oil types is summarized in Table 1 - **See separate datafile “GOED – Levels MCPD GEs in EPA DHA oils - v.010518”**. The identities of the specific omega-3 fish oil producers have been anonymized. Information is provided by the type of oil when possible, since the different oil types and stage of oil processing could have a marked influence on the levels of these contaminants. To facilitate the understanding of what the various oil types are, each sample is cross-referenced to a diagram prepared for more easy understanding. (**See separate diagram**).



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It appears that the type of oil affects the content of these process contaminants. Crude fish oil starts out with low, virtually undetectable levels of these contaminants, but a refined oil that has not been concentrated (similar to a refined vegetable oil) may have higher levels. Interestingly, concentration of EPA and DHA from a refined oil to a triglyceride or ethyl ester concentrate appears to reduce the levels of these process contaminants, even though it requires further processing.

Our members have reported the following regarding the presence and production of these process contaminants:

- Anchovy/sardine refined oils (often called “1812” oils): These process contaminants are not normally present in significant amounts unless high temperature processing (distillation and/or deodorization) is utilized, which is used to further improve the sensory experience. However, in the case of bottled liquid oils or encapsulated oils with improved sensory properties, which are more heavily deodorized, there could be a potential risk for MCPD development.
- Tuna oils: Depending on the processing conditions, levels up to 5 mg/kg of 3-MCPD have been observed. Tuna oils that have not been subjected to distillation/deodorization show very low levels near the limit of detection.

We believe that the same logic applies to other fish oils - as the heat intensity of distillation/deodorization increases, the level of MCPDs increases.

- One of our members reports that MCPD contents in fish oils depend mainly on the refining/refining technology. According to their experience, the following levels have been found in EPA/DHA omega-3 oils:

Refining technology	2-MCPDs	3-MCPDs
not deodorized/distilled oil	<0.2mg/kg	<0.5mg/kg
distilled fish oils	≤ 0.2mg/kg	≤ 1mg/kg
high temp. deodorized oils	~ 2mg/kg	~ 5mg/kg

- One member that is a third-party testing laboratory has observed EPA/DHA-containing oils with 3-MCPD levels up to 10 mg/kg oil. Furthermore, in a set of approximately 60 fish oil samples from different countries (France, Japan, China, US, Germany, Netherlands, and Norway) the range of the total 3-MCPD level ranges from below the limit of quantitation (< 0.15 mg/kg) to 3.4 mg/kg. Of this set, approximately 10% of the oils did not contain 3-MCPDs (i.e. < 0.15 mg/kg).
- Krill oils: We have now included the first results on the levels in krill oils. No detectable levels of the process contaminants were found.



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- For concentrates and re-esterified triglycerides, the levels of the process contaminants vary from oil to oil. The precise conditions that have been employed by each producer will determine the final levels. Overall, a large proportion of oils appear to have levels close to the limit of detection, many have levels below 1 mg/kg and the majority below 3 mg/kg. Exceptions of oils with higher levels have been detected as well.

2. Recommended levels for 2-MCPD, 3-MCPD, their esters, and glycidyl esters, in fish oils and EPA-/DHA-rich omega-3 oils, if a level would need to be set.

GOED, representing a major part of the fish oil industry and EPA/DHA-containing oil producers and a significant portion of finished product manufacturers, recommends that maximum limits for 2-MCPD, 3-MCPD, glycidol or their esters in fish oils are not established until a systematically obtained set of data on the levels in commercially available fish oils can be considered and exposure to consumers of these compounds from fish oils can be determined. If a systematic effort to evaluate the levels of these process contaminants in finished products has already been undertaken, GOED would like to be able to view the obtained data if possible.

Available data for these process contaminants is based mainly from bulk oil producers, rather than from finished products. Currently we have a near complete lack of information for fish oil and EPA-/DHA-rich oil-containing finished products on the European market, as well as in other countries. As we do not know the contribution/impact of further processing/formulation, it is important to gather this data prior to establishing any limits on contaminant levels. Such a monitoring program should also seek to capture information on the specific type of fish oil or EPA/DHA-rich oil utilized because the source and the type of manufacturing process could affect the levels of these compounds present. Specifically, it should be noted whether the product is an unrefined oil, a refined oil, an ethyl ester concentrate, or a triglyceride concentrate. To illustrate the complexity of this matter, as an example, notable levels of diglycerides may again appear in specific processing steps, for example after enzymatic re-esterification employed in the production of concentrated triglycerides, or in dedicated diglyceride oil products. Some products purposefully contain EPA and DHA as part of a monoglyceride-enriched oil, for which the levels of the contaminants were low.

Furthermore, for a number of years, the vegetable oil industry has been actively monitored by EFSA, but this has not been the case for EPA/DHA-rich oils (fish body oils, fish liver oils, concentrates, other marine oils, and algae oils).

In addition, an exposure assessment should also take into account the average European exposure to these process contaminants from fish oils. The absolute volume of the dietary intake of fish oils/ EPA/DHA omega-3 oils as supplements is much lower than that of vegetable oils in the diet even among the highest percentiles of users. We believe targets should be set for the upper limits of MCPDs and glycidyl-esters based on the analysis of EFSA, but in addition should take into account the exposure from fish oil/



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EPA/DHA omega-3 supplements. These products are typically taken in dosages of 1-3g daily, and often lower for concentrated forms; whereas, daily intake of vegetable oils is significantly higher. Estimations of annual consumption of vegetable oils and fats in the European Union are 25,121,000 tons (year 2016, [FEDIOL](#)). GOED estimates that European consumption of EPA/DHA omega-3 supplements from fish oils and other sources is several hundred-fold lower at only 17,700 tons. EFSA has issued a Scientific Opinion summarizing the food sources containing EPA and DHA, including dietary supplements, as well as the mean daily intakes of EPA, docosapentaenoic and DHA (year 2012, [EFSA](#) Scientific Opinion).

We would also like to stress that fish oils are only one segment of oils containing EPA and DHA or other omega-3 long-chain polyunsaturated fatty acids. Oils obtained from algae and krill form part of the spectrum of EPA/DHA-rich oils but are not fish oils. Discussing limit setting for EPA/DHA omega-3-containing oils appears more appropriate, in particular with a view to being clear what products any future limits will apply.

If a maximum level for 3-MCPD, 2-MCPD and their fatty acid esters and glycidyl esters is proposed for EPA/DHA-rich oils, an implementation time would be desirable in order for those producers and finished product manufacturers to be able to make any adaptations to their production processes if necessary.

Sincerely,

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