



GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3S

European Commission  
c/o Working group “Industrial and Environmental Contaminants “

*Re: Stakeholder consultation on draft levels for 3-MCPD for vegetable and fish oils and glycidol esters for fish oils*

30 October 2018

Dear Sir or Madam:

The Global Organization for EPA and DHA Omega-3s (GOED) would like to thank the European Commission (EC) for opening a stakeholder consultation on possible maximum levels for 3-MCPD and glycidol esters (fish oils) and appreciates the opportunity to provide comments.

GOED is a trade organization and 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).

This letter provides comments by GOED on the consultation draft.

**Suggested possible maximum limits for glycidyl esters and the sum of free 3-monochloropropanediol (3-MCPD) and 3-MCPD fatty acid esters, expressed as 3-MCPD in fish oils placed on the market for the final consumer or for use as ingredient in food.**

Over the past two years GOED has been collecting information on the levels of these process contaminants in EPA/DHA-rich oils, including natural triglycerides, ethyl ester concentrates and reconstituted-triglyceride concentrates. We currently have data on some 200 batches provided by 19 of our members. GOED has calculated that, based on the information currently available, that for refined fish oils, concentrates and re-esterified triglycerides combined, the non-compliance with the proposed levels would be approximately 14% of member oils for 3-MCPD (total esters plus free) and 5.5% for glycidyl-esters. Based on our current information, GOED considers that the proposed maximum limits for categories 4.2.5 (1000 µg/kg) and 4.3.1 (2500 µg/kg) are acceptable in view of this low rate of non-compliance.

However, in view of achieving consistency with the proposed tolerable daily intake (TDI) by EFSA, GOED likes to point out that the intake of vegetable oils in food is not comparable with the intake of omega-3 supplements. Vegetable oils have much higher dosages per day. The recommended daily intake of omega-3 supplements ranges between 0.5 g and 5 g, being 0.5 - 2 g per day the most usual dosage and



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1 teaspoon (ca 5 g) among the highest dosage. The latest TDI proposal from EFSA is 2.0 µg/kg bw for 3-MCPD<sup>1</sup>.

This means that for a person of 50 kg, the TDI would be 100 µg 3-MCPD, and for a person of 100 kg, the TDI would be 200 µg 3-MCPD. Taking this into account, a maximum of 5000 µg/kg for 3-MCPD (total) would be more consistent. One teaspoon (ca 5 g) of an oil with 5000 µg/kg 3-MCPD would give an intake of 25 µg 3-MCPD, which is still far below the proposed TDI of 2.0 µg/kg bw. Limits for glycidol and its esters might stay at 1000 µg/kg for there is no TDI, according to EFSA's original report<sup>2</sup>.

### **Clarity on the proposed draft**

GOED suggests providing clarification on the following points in the proposed draft:

- The EU proposed limit for 3-MCPD (2500 µg/kg) and glycidol (1000 µg/kg) refers to “oils placed on the market for the final consumer or for use as an ingredient in food”. Does this include food supplements?
- In sections 4.2.5 and 4.3.1 the proposal refers to “oils placed on the market for the final consumer or for use as an ingredient in food” with the exception of baby foods, but does not exclude infant formula, follow-on formula and foods for special medical purposes intended for infants and young children. Does this mean that 4.2.5 and 4.3.1 apply to ingredient oils used for infant formula, follow-on formula and foods for special medical purposes intended for infants and young children?
- In sections 4.2.5 and 4.3.1 is reference to fish oils inclusive of all marine oils or just fish oils? It should be noted that other marine oils, such as krill oil, squid oil and calanus oil, can be and are used in foods. Are EPA/DHA-rich oils from a marine, but non-fish, origin considered to be “fish oils.” Codex Alimentarius classifies high phospholipid products (e.g. krill oil) as fish oil<sup>3</sup>, but the EC has not provided guidance on this point.
- GOED would like to point out to the EC that algal oils, and other microbial oils, are currently considered vegetable oils. According to one of our European algae oil producers, algae oils are considered vegetable oils and need to be refined in a refinery for vegetable oils, and would hence fall under the proposed limits for vegetable oils. So, for an algae oil in ethyl ester or re-esterified triglyceride form, because the origin is “vegetable” it is still a vegetable oil. Another European member of our association has indicated that their microbial oils (algal and fungal oils) fall within the category vegetable oils, are considered as “vegetarian sourced”, and they have always used the levels for vegetable oils as their reference.

<sup>1</sup> <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2018.5083>

<sup>2</sup> <https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2016.4426>

<sup>3</sup> [http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252Fstandards%252FCODEX%2Bstan%2B329-2017%252FCXS\\_329e.pdf](http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252Fstandards%252FCODEX%2Bstan%2B329-2017%252FCXS_329e.pdf)



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As an alternative approach, GOED would like to suggest the EC specify limits for "single cell oils" which could encompass oils from algae, fungi and protists, in addition to "fish oils"/"marine oils" and vegetable oils. In any case, we want to be sure there is clarity that these single cell oils will not fall between the meanings of vegetable oil and fish oil.

Examples of microbial organisms that are used for the production of single cell oils (rich in DHA) for infant formula are *Cryptocodinium cohnii*, *Mortierella*, and *Schizochytrium*.

- Fish oil is not mentioned in Section 4.3.2. "Vegetable oils and fats destined for the production of baby foods and processed cereal based foods for infants and young children." Does this mean fish oils (and perhaps other marine oils and single-cell oils pending clarification above) are exempt from the proposed level of 750 µg/kg for these food categories?
- Levels of 3-MCPD and GE for fish and vegetable oils would need to meet specific limits for foods (4.2.5 and 4.3.1). Does that include infant formulas? One may assume infant formula is a food (see above). Levels of 3-MCPD and GE for oils for baby foods have different maximum limits. What about fish oils used for baby foods? No information is currently provided, only vegetable oils are mentioned.
- The text is currently ambiguous about there being no proposed limits for fish oils used as ingredient oils in the manufacturing of infant formula, because in 4.2.5 (glycidyl-esters) and 4.3.1 (3-MCPD) it is currently not clear that "food" does or does not include infant formula. A lack of limits related to the use of fish oils as ingredients to infant formula, follow-on formula and foods for special medical purposes intended for infants and young children is expected to lead to a situation where infant formula producers set their own limits for these contaminants. Infant formula manufacturers tend to be conservative and are very risk averse as they do not want recall issues, so if there is some ambiguity in a specification they will always go low. Without guidance on fish oils (or, see above, fish/marine oils, and single cells oils) in 4.2.2 and 4.3.2 on the ingredient fish oils, these companies ask for fish oil for infant formula with the levels that are set for the final product (i.e. in 4.2.3, 4.2.4 and 4.3.3 and 4.3.4), as that would be the safest route for them to ensure the final levels. One interpretation that regulators may take is that the words in 4.2.2 and 4.3.2 "destined for the production of baby food" imply that the oil must meet those conditions if it is being used to make infant formula (as infant formula is one form of baby food, and the words in 4.2.2 do not say "destined for the production of baby food, excluding infant formula").

GOED likes to ask the Commission for guidance and clarification on this issue. The current proposal appears to state that these limits are only for the end product sold, but this should be made more clear. Our concern is that without a specific mention of "fish oil" and other marine, algal or single-cell oils (generally rich in DHA) in 4.2.2 and 4.3.2, or an explicit mention of the exclusion of infant formula, customers/regulators will either say the limit for use in infant formula is non-detectable or set an artificially low specification. According to reports we have received, this is already happening in the marketplace for glycidyl esters and is expected to happen with 3-MCPD as well.



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In addition, for infant formula and foods for special medical purposes, the loadings of fish oil in the end formulation are not always known and likely vary between products, precluding a generalized back calculation of the required maximum levels in DHA-rich oils. However, DHA-rich oils are used in significantly lower levels than are vegetable oils. As an example, inclusion of microencapsulated DHA spray-dried oil powder into infant formula is between 0.5-1.0%. The total lipids in infant formula are generally around 30%, and that is vegetable oil and omega-3 oils. Hence there is a ratio of approximately 29:1 vegetable oil: DHA-rich oil in infant formula. With those ratios it would not make sense to set maximum limits for DHA-rich fish or marine oils/single cell oils that are as strict as those for vegetable oils.

### **Analytical Methods**

Sections 4.3.3 and 4.3.4 propose limits for 3-MCPD in “infant formula, follow-on formula and foods for special medical purposes intended for infants and young children” that are extremely low (powder: 125 µg/kg and liquid: 15 µg/kg). The limit of quantification (LOQ) by one specialist laboratory in our membership that measures total 3-MCPD (free and bound) in foods with a fat content higher than 1% is 10 µg/kg. The best currently available method is therefore barely sensitive enough, in theory, to measure 3-MCPD (total). In practice, LOQs are often reported higher than what the method states. For example, the LOQ for 3-MCPD in oils is 100 µg/kg, but customers receive an LOQ of 150 µg/kg reported on their certificates of analysis if there was some unforeseen interference in the analysis. Several companies have expressed concern that current methods for infant formula are not yet sufficiently developed. We think more time and information is needed before establishing limits for 3-MCPD in “infant formula, follow-on formula and foods for special medical purposes intended to infants and young children”.

### **An appropriate transition**

It is very important for the continuity of commerce in the EU that an appropriate transition period is granted prior to full enforcement of 3-MCPD and glycidol esters (fish oils). Manufacturers of vegetable and fish oils and final infant formulas products require a suitable time frame to ensure that all products will meet the proposed levels. A transition period of ‘no less than’ 6 months from the date proposed levels are published in the EU Official Journal is strongly urged to ensure compliance and continuity of commerce.

Sincerely,

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