GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3S

Date: June 2, 2025

Food and Agriculture Organization (FAO) of the United Nations
ATTN: Maura Di Martino, PhD
Viale delle Terme di Caracalla
00153 Rome, Italy
sent electronically to Maura.DiMartino@fao.org

**RE: Request to update information in** *Food safety in personalized nutrition – A focus on food supplements and functional foods* related to EPA and DHA's purported risk of bleeding

Dear Dr. Di Martino:

GOED, the Global Organization for EPA and DHA Omega-3s, represents the worldwide EPA and DHA omega-3 industry, with a membership built on a quality standard unparalleled in the market. Members must comply with quality and ethics guidelines that ensure they produce quality products that consumers can trust. Our 200+ members and partners represent the entire supply chain of EPA and DHA omega-3s, from fisheries and crude oil suppliers to refiners, concentrators and finished product brands. Our mission is to use science-based information to promote consumption of and enable access to quality EPA and DHA from all sources for a positive impact on public health.

GOED writes regarding FAO's recent publication *Food safety in personalized nutrition – A focus on food supplements and functional foods.*[1] This publication was an enormous undertaking, and we applaud your work. In the interest of using accurate science-based evidence to educate consumers about EPA and DHA, we would like to provide some comments for your consideration about EPA and DHA as it relates to bleeding risk.

Our comments are related to Table 2 (page 16), and the impact of omega-3s on pre-existing medical conditions (page 22).

[1] https://openknowledge.fao.org/items/d822409d-272c-4680-a386-d4fa03227c27

**Table 2 – Interactions with Foods and Pharmaceuticals**

Table 2 (beginning on page 16) provides "examples of interactions between drugs and bioactive ingredients contained in food, food supplements and functional foods" and includes "Fish oil/ Omega-3 fatty acids" potentially interacting with anticoagulants, non-steroidal anti-inflammatory drugs and platelet aggregation to increase bleeding risk.

- The referenced article in the table, "Safety issues and harmful pharmacological interactions of nutritional supplements in Duchenne muscular dystrophy: considerations for Standard of Care and emerging virus outbreaks" from Boccanegra et al,[2] details a population with Duchenne muscular dystrophy and should not be used to generalize to the overall population.
    - Instead, we recommend referencing "Bleeding Risk in Patients Receiving Omega-3 Polyunsaturated Fatty Acids: A Systematic Review and Meta-Analysis of Randomized Clinical Trials" from Javaid et al,[3] a more recent and comprehensive review.
- We suggest removing the comments about "Fish oil / Omega-3 fatty acids" potentially interacting with anticoagulants, non-steroidal anti-inflammatory drugs and platelet aggregation to increase bleeding risk as this is inaccurate. Javaid et al conclude that the intake of EPA and DHA is not associated with an increase in bleeding risk or increase in bleeding events. The authors also reiterate that EPA and DHA omega-3s are not potent anti-coagulants, in comparison to pharmaceuticals. GOED has also undertaken its own review of the literature – including 101 articles - related to bleeding risk. Almost all studies reported a non-significant difference between the treatment group and the placebo group regarding bleeding events. We are preparing a manuscript for submission to a peer-reviewed journal and would be happy to share it once accepted for publication.
- With respect to the interaction of omega-3s and non-steroidal anti-inflammatory drugs (NSAIDs), Boccanegra et al wrote, "…PUFA may have interactions with NSAIDs," but they did not provide any reference or indication which NSAID might be of concern. While GOED assumes the NSAID of concern is aspirin, we are not aware of any credible evidence that taking the two together increases the risk of bleeding events.

[2] https://pmc.ncbi.nlm.nih.gov/articles/PMC7261230/
[3] https://pmc.ncbi.nlm.nih.gov/articles/PMC11179820/

**Impact of Omega-3s on Pre-Existing Medical Conditions**

On page 22 the text reads: "…in the context of cardiovascular health, it is crucial to consider the impact of bioactive compounds like omega-3 fatty acids, which are prevalent in many food supplements. While these compounds could potentially offer health benefits, excessive intake may lead to adverse effects, especially in individuals with blood clotting disorders (Li, Fu and Koonen, 2018)."

- No clinically relevant bleeding-related adverse events have been reported in the general population, or for individuals with clotting disorders. The Javaid et al publication supports this point. Only one trial (REDUCE-IT)[4] reported that high-dose EPA increased bleeding risk and the clinical significance is debatable. The dose of EPA is related to the level of risk, rather than the background use of anticoagulant and antiplatelet therapy.
- We were unable to find the cited reference (Li, N., Fu, J. & Koonen, D. 2018. Omega-3 fatty acids and their impact on cardiovascular disease: Potential risks associated with uncontrolled supplementation. *Journal of Clinical Nutrition*, 105(3): 1428–1440). Thus, we couldn't verify the statement about adverse effects. We suggest replacing this reference if a suitable one can be found; otherwise, the commentary should be removed.

[4] https://www.nejm.org/doi/full/10.1056/NEJMoa1812792

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In summary, GOED believes it's important to dispel the persistent misconceptions about intake of EPA and DHA and bleeding risk and we respectfully suggest updating the information on this topic in your publication to align with the most comprehensive science on this issue.

We would be happy to discuss further or answer any questions.

Sincerely,

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