



GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3S

1 August 2022

Taiwan Food and Drug Administration
Ministry of Health and Welfare
No.161-2, Kunyang St, Nangang District
Taipei City 115-61, Taiwan
Sent via email to fan@fda.gov.tw

RE: *Revised Draft Regulations Governing the Labeling of Health Food*

To Whom It May Concern:

GOED, the Global Organization for EPA and DHA Omega-3s, represents the worldwide EPA and DHA omega-3 industry, with a mission to increase consumption of EPA and DHA omega-3s around the world. The membership is built on a quality standard unparalleled in the market and members must comply with quality and ethics guidelines that ensure members produce quality products that consumers can trust. Our 160+ members represent the entire supply chain of EPA and DHA omega-3s, from fisheries and crude oil suppliers to refiners, concentrators and finished product brands.

GOED appreciates the opportunity to provide comments on the *Revised Draft Regulations Governing the Labeling of Health Food* notified (G/TBT/N/TPKM/493) to the World Trade Organization (WTO) on 3 June 2022. GOED's comments are specific to point 6 – “Health food with fish oil shall be labeled ‘Infants, pregnant women, patients with diabetes mellitus or the people with abnormal blood coagulation taking anticoagulant are suggested to ask doctor’s recommendations before eating’ or other similar statements with the same meaning in the warnings on containers or packages.”

While GOED supports the use of warnings when appropriate, there is no reason for the proposed warning statements. In fact, the opposite is true for some of the groups mentioned. In particular, Infants and pregnant women should be encouraged to consume more fish oil, a source of the beneficial fatty acids eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). Furthermore, GOED is concerned that your warning statement could have the unintended consequence of deterring people who would benefit the most from taking products with EPA/DHA. Each of the four groups identified in the warning statement will be discussed below.

Infants

Perhaps the best evidence that omega-3s are beneficial (not detrimental) for infants is the European Commission’s authorization of the following health claim - *Docosahexaenoic acid (DHA) intake contributes to the normal visual development of infants up to 12 months of age.*¹

¹Commission Regulation (EU) No 440/2011 of 6 May 2011 on the authorisation and refusal of authorisation of certain health claims made on foods and referring to children’s development and health <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32011R0440>



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Pregnant Women

The European Commission also authorized the use of two health claims when marketing products to pregnant women.

- 1) *Docosahexaenoic acid (DHA) maternal intake contributes to the normal brain development of the foetus and breastfed infants.*¹
- 2) *Docosahexaenoic acid (DHA) maternal intake contributes to the normal development of the eye of the foetus and breastfed infants.*¹

In addition to the two European health claims, there is strong evidence² that omega-3 supplementation during pregnancy reduces the risk of pre-term and early pre-term birth. This research serves as the basis for published guidelines³ in Australia advising pregnant women with low omega-3 status to supplement with 800 mg/day DHA and 100 mg/day EPA.

People with Abnormal Blood Coagulation Taking Anticoagulant

The idea that EPA/DHA cause bleeding issues is outdated and is based upon a report from over 30 years ago.⁴ The de facto three gram limit, which has been promulgated globally, was in place until 19 June 2019, when the US FDA responded in a letter of enforcement discretion⁵ to a health claim petition submitted by GOED. A safety review is included on pages six through nine. "With regard to bleeding risk, we concluded that consumption of less than or equal to 5 grams/day of EPA and DHA does not increase the risk of excessive bleeding based on clinical trials that measured clinical outcomes such as bleeding episodes and blood loss." For your reference, a more extensive review of the scientific literature on EPA and DHA intake and risk of excessive bleeding is provided in an FDA memo.⁶

Patients with Diabetes Mellitus

Using the GOED Clinical Study Database,⁷ a compilation of all human studies on omega-3s, there is no evidence that EPA/DHA are harmful for this population and there could be a benefit.⁸ In addition,

²Middleton P, Gomersall JC, Gould JF, Shepherd E, Olsen SF, Makrides M. Omega-3 fatty acid addition during pregnancy. *Cochrane Database Syst Rev.* 2018 Nov 15;11(11):CD003402. doi: 10.1002/14651858.CD003402.pub3. PMID: 30480773; PMCID: PMC6516961. <https://pubmed.ncbi.nlm.nih.gov/30480773/>

³Australian Government Department of Health and Aged Care (2020). *Pregnancy Care Guidelines.*

<https://www.health.gov.au/resources/pregnancy-care-guidelines/part-c-lifestyle-considerations/nutrition-and-physical-activity#112-nutritional-supplements>

⁴Hsia, M.T.S., Marvis, R.D., DeSesso, J.M., 1989. Health Effects of Refined Menhaden Oil. Prepared by Mitre Corp., Civil Systems Division, McLean, Virginia for US Food and Drug Administration (US FDA), Washington, DC (PB89-182398).

⁵Letter Responding to Health Claim Petition dated April 24, 2014: "Eicosapentaenoic Acid and Docosahexaenoic Acid and Reduction of Blood Pressure in the General Population" (June 19, 2019). <https://www.fda.gov/media/128043/download>

⁶<https://downloads.regulations.gov/FDA-2014-Q-1146-0094/content.pdf>

⁷Bernasconi AA, Wilkin AM, Roke K, Ismail A. Development of a novel database to review and assess the clinical effects of EPA and DHA omega-3 fatty acids. *Prostaglandins Leukot Essent Fatty Acids.* 2022 Jun 23;183:102458. doi: 10.1016/j.plefa.2022.102458. Epub ahead of print. PMID: 35816925. <https://pubmed.ncbi.nlm.nih.gov/35816925/>

⁸Delpino FM, Figueiredo LM, da Silva BGC, da Silva TG, Mintem GC, Bielemann RM, Gigante DP. Omega-3 supplementation and diabetes: A systematic review and meta-analysis. *Crit Rev Food Sci Nutr.* 2022;62(16):4435-4448. doi: 10.1080/10408398.2021.1875977. Epub 2021 Jan 22. PMID: 33480268. <https://pubmed.ncbi.nlm.nih.gov/33480268/>



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the above referenced safety review from the FDA included an evaluation on glycemic control. “After searching FDA’s adverse event report database and evaluating relevant studies on EPA and DHA, we concluded that EPA and DHA intake up to 10 g/day appears to have no adverse effect on glycemic control, as measured by fasting blood glucose and HbA1c.” For your reference, a more extensive review of the scientific literature on EPA and DHA intake on glycemic control is provided in an FDA memo.⁹

To conclude, GOED encourages the Taiwan FDA to reconsider its requirement that health food with fish oil be labeled with an unsubstantiated warning statement.

Thank you in advance for your consideration of our feedback. Should you have any questions about our comments, please let us know. We are at your disposal, now and in the future, to answer any EPA/DHA related questions.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Harry B. Rice', written over a faint, light blue circular watermark or seal.

Harry B. Rice, Ph.D.
Vice-President, Regulatory & Scientific Affairs

⁹<https://downloads.regulations.gov/FDA-2014-Q-1146-0093/content.pdf>