GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3S

14 November 2025

European Food Safety Authority's (EFSA) Nutrition and Food Innovation Unit

RE: PC-1647 *Draft scientific opinion on the safety of supplemental docosahexaenoic acid (DHA)*[1]

Dear Nutrition and Food Innovation Unit:

We write on behalf of GOED, the Global Organization for EPA and DHA Omega-3s, regarding the Draft Scientific Opinion on the Tolerable Upper Intake Level for Supplemental Docosahexaenoic Acid (DHA).

GOED represents the worldwide eicosapentaenoic (EPA) and docosahexaenoic acid (DHA) industry, with a membership built on a quality standard unparalleled in the market. Our 200+ members, which represent the entire EPA & DHA supply chain, must comply with quality and ethics guidelines that ensure they produce quality products that consumers can trust. Our mission is to use science-based information to promote consumption of and enable access to quality EPA & DHA from all sources for a positive impact on public health.

Pursuant to our mission, we appreciate the opportunity to provide feedback on the *Draft scientific opinion on the safety of supplemental docosahexaenoic acid (DHA)* associated with EFSA-Q-2025-00054.[2] We will focus our comments on "3.2.1 Bleeding complications, bleeding time, platelet function and blood clotting parameters." Further, since "…the Panel decided to select risk of spontaneous bleeding [and bleeding complications] as the critical effect on which to base the UL/safe level of intake for supplemental DHA alone," we will comment specifically on spontaneous bleeding / bleeding complications.

GOED would like to bring to your attention the following studies (additional details found in the Appendix) which provide 1200-1900 mg/day of DHA. These do not appear in the draft scientific opinion, but could be relevant to your review of spontaneous bleeding / bleeding complications.

- Marc I, Piedboeuf B, Lacaze-Masmonteil T, Fraser W, Mâsse B, Mohamed I, et al. Effect of Maternal Docosahexaenoic Acid Supplementation on Bronchopulmonary Dysplasia-Free Survival in Breastfed Preterm Infants: A Randomized Clinical Trial. JAMA. 2020 Jul 14;324(2):157-167. doi: 10.1001/jama.2020.8896. PMID: 32662862; PMCID: PMC7361648. https://pubmed.ncbi.nlm.nih.gov/32662862/

- Pellonperä O, Mokkala K, Houttu N, Vahlberg T, Koivuniemi E, Tertti K, et al. Efficacy of Fish Oil and/or Probiotic Intervention on the Incidence of Gestational Diabetes Mellitus in an At-Risk Group of Overweight and Obese Women: A Randomized, Placebo-Controlled, Double-Blind Clinical Trial. Diabetes Care. 2019 Jun;42(6):1009-1017. doi: 10.2337/dc18-2591. Epub 2019 Apr 9. PMID: 30967436. https://pubmed.ncbi.nlm.nih.gov/30967436/

- Soininen H, Solomon A, Visser PJ, Hendrix SB, Blennow K, Kivipelto M, et al. LipiDiDiet clinical study group. 36-month LipiDiDiet multinutrient clinical trial in prodromal Alzheimer's disease.

[1] https://connect.efsa.europa.eu/RM/s/consultations/publicconsultation2/a0lTk000005kBvF/pc1647
[2] https://open.efsa.europa.eu/question/EFSA-Q-2025-00054

Alzheimers Dement. 2021 Jan;17(1):29-40. doi: 10.1002/alz.12172. Epub 2020 Sep 13. Erratum in: Alzheimers Dement. 2021 May;17(5):909. doi: 10.1002/alz.12346. PMID: 32920957; PMCID: PMC7821311.
https://pubmed.ncbi.nlm.nih.gov/32920957/

While it's possible the studies were excluded during the screening process, they don't appear in "Table B2. Human intervention studies excluded at data extraction and reasons for exclusion (line 1089)." Of relevance is that these three studies, which provided 1200-1900 mg/day of DHA, did not find a difference in spontaneous bleeding / bleeding complications between the intervention group (i.e. DHA) and the control group.

We identified these studies using our internal Clinical Study Database (CSD),[3] which allows us to search and organize research on EPA & DHA by cataloging articles indexed in PubMed. Each potentially relevant article is imported into the CSD and reviewed by two scientists, and a third in case of disagreement.

For interventional trials, the CSD includes detailed data such as participant numbers, baseline characteristics, interventions and placebos, and measured outcomes. Unlike standard PubMed searches, which rely on author- or system-defined keywords, the CSD enables searches by all outcomes measured, even if they are not listed in the title, abstract or MeSH terms. For example, bleeding is often measured in clinical trials but rarely appears as a keyword. The CSD allows us to identify all studies that measured bleeding, regardless of whether it was a primary outcome. Using this capability, we identified the three references related to spontaneous bleeding / bleeding complications that we did not see mentioned in the draft scientific opinion.

Once again, thank you for the opportunity to provide comments for your consideration as you finalize your scientific opinion. We remain at your disposal should any questions arise.

Sincerely,

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[3] https://pubmed.ncbi.nlm.nih.gov/35816925/

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Appendix: Missing studies providing 1200-1900 mg/day of DHA

Reference & Country	Study Design	Population	Age (yrs) and sex	N per DHA arm (completers)	DHA dosage (mg)	DHA source	EPA dosage (mg)	EPA/DHA ratio	Comparator	Duration	Endpoints
Marc I, Piedboeuf B, Lacaze-Masmonteil T, Fraser W, Mâsse B, Mohamed I, et al. Effect of Maternal Docosahexaenoic Acid Supplementation on Bronchopulmonary Dysplasia-Free Survival in Breastfed Preterm Infants: A Randomized Clinical Trial. JAMA. 2020 Jul 14;324(2):157-167. doi: 10.1001/jama.2020.8896. PMID: 32662862: PMCID: PMC7361648. Canada	DB-RCT*	Pregnant women	31 +/- 5 years old	232 mothers in the DHA group	1200	algae, Schizochytrium	100	0.083	contained 50% soy oil and 50% corn oil	Delivery until infant reached 36 weeks postmenstrual age (ranged from 8-13 weeks)	Mothers' bleeding
Pellonperä O, Mokkala K, Houttu N, Vahlberg T, Koivuniemi E, Tertti K, et al. Efficacy of Fish Oil and/or Probiotic Intervention on the Incidence of Gestational Diabetes Mellitus in an At-Risk Group of Overweight and Obese Women: A Randomized, Placebo-Controlled,	DB-RCT*	Pregnant women	30-31 +/- 4-5 years old	110 in DHA group	1900	fish oil	220	0.116	equal amount of medium-chain fatty acids (capric acid C8 54.6% and caprylic acid C10 40.3%) and were of the same size, shape, color, and lemon	Throughout pregnancy until 6 months postpartum	Postpartum hemorrhage

Double-Blind Clinical Trial. Diabetes Care. 2019 Jun;42(6):1009-1017. doi: 10.2337/dc18-2591. Epub 2019 Apr 9. PMID: 30967436. Finland									flavor as the fish oil capsules		
Soininen H, Solomon A, Visser PJ, Hendrix SB, Blennow K, Kivipelto M, et al. LipiDiDiet clinical study group. 36-month LipiDiDiet multinutrient clinical trial in prodromal Alzheimer's disease. Alzheimers Dement. 2021 Jan;17(1):29-40. doi: 10.1002/alz.12172. Epub 2020 Sep 13. Erratum in: Alzheimers Dement. 2021 May;17(5):909. doi: 10.1002/alz.12346. PMID: 32920957; PMCID: PMC7821311. Across sites in Finland, Germany, the Netherlands and Sweden	DB-RCT*	Adults	69-72 +/- 7 years	45 in the DHA group	1200	Souvenaid, a 125 mL once-a-day drink containing a specific multinutrient combination, including DHA	300	0.25	125 mL once-a-day control drink. The control drink is isocaloric, similar in appearance and flavor to the active study product, but without Fortasyn Connect	36 months	Hemorrhage

*Double-blind randomized controlled trial (DB-RCT)