



GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3S

注：此为英文翻译件

2025年5月8日

关于：《保健食品原料 鱼油》国家标准（征求意见稿）的意见反馈

致有关单位：

全球 EPA 及 DHA Omega-3 组织（GOED）是代表全球二十碳五烯酸（EPA）和二十二碳六烯酸（DHA）Omega-3 脂肪酸行业的国际组织，以推动全球 EPA 和 DHA Omega-3 脂肪酸消费为使命。GOED 拥有 200 余家会员企业（包括多家中国企业），建立了一套基于市场过硬的质量标准体系。GOED 会员企业必须遵守质量与伦理准则，确保其生产值得消费者信赖的优质产品，并对公众健康产生积极影响。GOED 谨就《保健食品原料 鱼油》国家标准（征求意见稿）提出以下建议。

GOED 的意见主要针对 EPA+DHA 含量上限 70g/100g 此技术指标。鉴于高浓度鱼油安全使用的长期历史，GOED 担心该含量上限的设定可能限制 GOED 会员企业在中国市场销售 EPA+DHA 含量超过 70g/100g 的鱼油产品。该含量上限规定与食品法典委员会《鱼油标准》（CXS 329-2017）¹存在直接冲突（《鱼油标准》并未对高浓度鱼油设置含量上限），将限制具有明确健康效益产品的市场准入。此外还将导致中国市场相关在售产品被迫退市。事实上，《〈保健食品原料 鱼油〉国家标准（征求意见稿）编制说明》中表3保健食品鱼油原料代表性样品标志性成分检测数据表明，中国市场上近 20%的鱼油原料 EPA+DHA 含量超过 70g/100g。

就安全性而言，现有数据尚不足以确定任何人群的 EPA+DHA 的可耐受最高摄入量（UL），但多家政府机构已表明，当 EPA+DHA 日摄入量达到 5.0-6.9 克/天时未见不良反应²³⁴，该摄入量已经远超普通 Omega-3 补充剂使用者的实际摄入水平。

综上，GOED 建议取消该 EPA+DHA 含量上限规定。

¹ https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B329-2017%252FCXS_329e.pdf

² [Norwegian Scientific Committee for Food Safety \(VKM\)](#)

³ [European Food Safety Authority \(EFSA\)](#)

⁴ [United States Food and Drug Administration \(FDA\)](#)



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感谢贵方对 GOED 所提意见的考量。如有任何疑问，请随时与我们联系。

此致

全球 EPA 及 DHA Omega-3 组织

Global Organization for EPA and DHA Omega-3s

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

Harry B. Rice 博士
法规与科学事务副总裁

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Gabriela A. Cortez R.,
Regulatory & Technical Support Manager

MSc Gabriela A. Cortez R.理学硕士
法规与技术支持经理

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Gerard Bannenberg, PhD
Director, Technical Compliance & Outreach

Gerard Bannenberg 博士
技术合规与推广总监



GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3S

May 8, 2025

RE: Draft National Standard for Health Food Raw Material Fish Oil

To Whom It May Concern:

GOED, the Global Organization for EPA and DHA Omega-3s, represents the worldwide eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) omega-3 industry, with a mission to increase consumption of EPA and DHA omega-3 fatty acids around the world. GOED has more than 200 member companies, including many based in China, and our membership is built on a quality standard unparalleled in the market. Our members must comply with quality and ethics guidelines that ensure they produce quality products that consumers can trust to ensure a positive impact on public health. GOED appreciates the opportunity to provide comments regarding the Draft National Standard for Health Food Raw Material Fish Oil.

GOED's comments are specific to the proposed specification for the EPA+DHA upper concentration limit of 70g/100g. Given the history of safe use of highly concentrated fish oils, GOED is concerned about the adoption of an upper concentration limit that will restrict GOED members' ability to continue selling fish oils that exceed 70g/100g in China. Not only is the adoption of an upper concentration limit in direct conflict with the Codex Standard for Fish Oils (CXS 329-2017),⁵ which does NOT include an upper concentration limit for highly concentrated fish oils, but it will restrict access to products with well-established health benefits. In addition, it would require the withdrawal of products currently sold on the Chinese market. In fact, according to Table 3 of the Preparation Notes, almost 20% of the fish oil raw material in China is greater than 70g/100g.

In terms of safety, the data have been insufficient to establish a tolerable upper intake level (UL) for EPA+DHA for any population, but several government agencies have documented an absence of adverse effects at observed intake levels of 5.0 – 6.9 grams/day of EPA+DHA.^{6, 7, 8} This level far exceeds the levels ingested by the average omega-3 supplement user.

To summarize, GOED recommends not adopting an upper concentration limit.

Thank you in advance for your consideration of GOED's comments. Should you have any questions, please do not hesitate to contact us.

⁵ https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B329-2017%252FCXS_329e.pdf

⁶ [Norwegian Scientific Committee for Food Safety \(VKM\)](#)

⁷ [European Food Safety Authority \(EFSA\)](#)

⁸ [United States Food and Drug Administration \(FDA\)](#)



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Sincerely,

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

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