

11 June 2021

Minister of Food and Drug Safety C/O Ministry of Food and Drug Safety Food Standards Division Osong Health Technology Administration Complex 187 Osongsaengmyeong2(i)-ro, Osong-eup, Heungdeok-gu, Cheongju-si Chungcheongbuk-do, Korea 28159

Email: intmfds@korea.kr

RE: Administrative Notice No. 2021-168 – Partial Revision of the Standards and Specifications of Health Functional Foods 1

Dear Minister:

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 writes to support Administrative Notice No. 2021-168, dated 20 April 2021, on the *Partial Revision of the Standards and Specifications of Health Functional Foods*, specifically the extension of the existing oxidation specifications (see below table) for EPA/DHA oils to include the finished retail oil products using said ingredients.

	Limit
Acid Value	3.0 KOH/g
Peroxide Value	5.0 meq/kg
p-Anisidine Value	20.0
TOTOX number	26.0

While we realize Acid Value was previously adopted as a quality parameter for ingredient EPA/DHA oils, we want to bring to your attention a limitation of this quality parameter. The GOED Voluntary Monograph,² which has served as the industry standard for quality since 2002,

¹https://www.mfds.go.kr/brd/m 209/view.do?seq=43461&srchFr=&srchTo=&srchWord=&srchTp=&itm seq 1=0 &itm seq 2=0&multi itm seq=0&company cd=&company nm=&page=2

²https://www.goedomega3.com/index.php/goed-monograph



was developed to help ensure that omega-3 oils reaching consumers were both safe and of high quality. The Monograph incorporates the strictest quality and purity standards from regulations around the world. While the Monograph used to include an Acid Value limit of 3.0 mg KOH/g, it was removed in 2015 because a single Acid Value limit can no longer be applied to the many different types of EPA/DHA products. For example, phospholipid-rich oils, such as krill oil, have much higher Acid Values. In fact, when the Codex Standard for Fish Oils (CXS 329-2017)³ was adopted in 2017, the Acid Value was set at \leq 3 mg KOH/g, with a higher value (\leq 45 mg KOH/g) allowed for phospholipid-rich oils like krill oil. GOED therefore suggests that the Ministry of Food and Drug Safety consider removing Acid Value from this regulation, both for ingredient oils and retail omega-3 products.

Lastly, GOED wants to confirm two points.

- 1) TOTOX number is used to describe the quality parameter associated with the limit of 26.0. It may be a result of the translation of Korean to English, but we have seen "Total Acid Value" used as the descriptor instead of "TOTOX number." Please confirm the wording is correct in the Korean version.
- 2) It appears that flavored oils are exempt from oxidation requirements, but we want to confirm, because some flavors, as well as colors, can interfere with the p-Anisidine Value assay, resulting in both p-Anisidine Values and TOTOX numbers exceeding the allowable limits.

In summary, GOED supports your decision to extend the same maximum limits for Peroxide Value, p-Anisidine Value and TOTOX number to retail products; however, we suggest you remove the applicability of Acid Value to omega-3 ingredient oils and retail products.

GOED appreciates your consideration of the above comments and would be happy to discuss them further at your convenience. Please do not hesitate to contact us.

Sincerely,

Harry B. Rice, PhD

VP, Regulatory & Scientific Affairs

harry@goedomega3.com

Gerard Bannenberg, PhD

Director, Compliance & Scientific Outreach

gerard@goedomega3.com