

25 November 2024

Dr. Alka Rao Advisor (Regulations, Science and Standards) Food Safety and Standards Authority of India (FSSAI) Ministry of Health and Family Welfare FDA Bhawan Kotla Road New Delhi, India advisor@fssai.gov.in

RE: Correction to 18 November 2024 Request

Dear Dr. Rao:

GOED, the Global Organization for EPA and DHA Omega-3s, writes to correct an error in last week's request (see attached) to change the requirement for krill oil to meet specifications for Peroxide Value and Totox number in the Amendment to the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011 published in the Gazette of India on 23 October 2024<sup>1</sup> regarding the changes found on pages 31-34 to sub-regulation 2.6.1, clause (12) relating to 'Sardine Oil.' Given that Anisidine (not Peroxide) Value cannot be determined in krill oils, we meant to request that you remove the Anisidine Value requirement. Our request to remove the Totox number requirement remains.

We apologize for any confusion that our last request may have caused. Thank you for your attention to this most recent request.

Sincerely,

Harry B. Rice, PhD VP, Regulatory & Scientific Affairs harry@goedomega3.com

Gerard Bannenberg, PhD Director, Technical Compliance & Outreach gerard@goedomega3.com

<sup>&</sup>lt;sup>1</sup>https://fssai.gov.in/upload/notifications/2024/10/671b28f9586dfGAZETTE%20NOTIFICATION%20DATED%20 21.10.2024.pdf



18 November 2024

Dr. Alka Rao Advisor (Regulations, Science and Standards) Food Safety and Standards Authority of India (FSSAI) Ministry of Health and Family Welfare FDA Bhawan Kotla Road New Delhi, India advisor@fssai.gov.in

RE: Amendment to the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011 published in the Gazette of India on 23 October 2024

Dear Dr. Rao:

GOED, the Global Organization for EPA and DHA Omega-3s, represents the worldwide EPA and DHA omega-3 industry, with a mission to use science-based information to promote consumption of quality EPA & DHA from all sources for a positive impact on public health. 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 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.

We write today concerning the Amendment to the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011 published in the Gazette of India on 23 October 2024<sup>1</sup> regarding the changes found on pages 31-34 to sub-regulation 2.6.1, clause (12) relating to 'Sardine Oil.'

We note the Codex Standard for Fish Oils (CXS 329-2017)<sup>2</sup> is duplicated in the Gazette Notification, with two exceptions. While the Codex Standard for Fish Oils (CXS 329-2017) does not require krill oil to meet either a Peroxide Value or Totox number, the Notification does. We believe this was an oversight that we would like to request be corrected.

When GOED reviewed the draft regulation and submitted general comments on 11 July 2022 (see attached letter), we did not realize that both Peroxide Value and Totox number were meant

<sup>&</sup>lt;sup>1</sup>https://fssai.gov.in/upload/notifications/2024/10/671b28f9586dfGAZETTE%20NOTIFICATION%20DATED%20 21.10.2024.pdf

<sup>&</sup>lt;sup>2</sup>https://www.fao.org/fao-who-codexalimentarius/shproxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252 FCXS%2B329-2017%252FCXS\_329e.pdf



to be applicable to krill oil. We suspect that the presentation of the quality parameters applicable to krill oil in a way that was different than the way they are presented in CXS 329-2017 resulted in our failure to detect the discrepancy. While we regret the oversight, given that Anisidine Value cannot be determined in krill oils (and hence Totox number cannot be calculated), which is why they are not required to do so in CXS 329-2017), we request the regulation be corrected.

GOED still stands by its 11 July 2022 suggestion to just make reference to the Codex Standard for Fish Oils (CXS 329-2017) which would eliminate the need to update the Food Safety and Standards (Food Products Standards and Food Additives) Regulations every time CXS 329-2017 is updated, which was first amended in 2021 and will be amended again in November should the 47<sup>th</sup> Session of the Codex Alimentarius Commission (CAC) vote in favor of the amendment/revision to include calanus oil.<sup>3</sup>

We appreciate your attention to this matter and would be happy to answer any questions you may have.

Sincerely,

Harry B. Rice, PhD VP, Regulatory & Scientific Affairs harry@goedomega3.com

Gerard Bannenberg, PhD Director, Technical Compliance & Outreach gerard@goedomega3.com

<sup>3</sup><u>https://www.fao.org/fao-who-codexalimentarius/sh-</u>

proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252F CX-701-47%252FWorking%2BDocuments%252Fcac47\_04e.pdf



Chief Executive Officer Food Safety and Standards Authority of India (FSSAI) FDA Bhawan, Kotla Road New Delhi, India 110002 Sent via email to regulation@fssai.gov.in

11 July 2022

Dear Chief Executive Officer:

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.

With respect to the Food Safety and Standards (Food Products Standards and Food Additives) Amendment Regulations, 2022<sup>1</sup> published in *The Gazette of India* on 25 May 2022, GOED writes to provide comments on the proposed changes to sub-regulation 2.6.1, clause (12) relating to 'Sardine Oil,' found on pages 32-35.

GOED agrees with the proposed substitution of 'Sardine Oil' with 'Fish Oil'; however, given that the proposed text is based on the Codex Standard for Fish Oils (CXS 329-2017),<sup>2</sup> GOED believes the proposed text in the draft clause for 'Fish Oil' should just refer to the Codex Standard for Fish Oil. This change would eliminate the need to update the Food Safety and Standards (Food Products Standards and Food Additives) Regulations in the future when changes are made to the Codex Standard for Fish Oils.

GOED, as a recognized Codex Observer,<sup>3</sup> was intimately involved in discussions about and adoption of this Standard. Given that the Delegation of India, which included two delegates from FSSAI at the 25<sup>th</sup> Session of the Codex Committee on Fats and Oils (CCFO), did not oppose forwarding the draft Standard for Fish Oils to the 40<sup>th</sup> Session of the Codex Alimentarius Commission (CAC) for adoption in 2017, GOED assumes FSSAI supports the standard as well.

Should you have any questions about our comments, please do not hesitate to contact us.

Sincerely,

Harry B. Rice, PhD Vice-President, Regulatory & Scientific Affairs harry@goedomega3.com

Gerard Bannenberg, Ph.D. Director, Technical Compliance & Outreach gerard@goedomeg3.com

<sup>2</sup> https://www.fao.org/fao-who-codexalimentarius/sh-

https://www.fssai.gov.in/upload/uploadfiles/files/Draft\_notification\_FPS\_FA\_31\_05\_2022.pdf

proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B329-2017%252FCXS\_329e.pdf <sup>3</sup> http://www.fao.org/fao-who-codexalimentarius/about-codex/observers/obs-list/en/