



GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3S

28 June 2018

Ministry of Food and Drug Safety via Brian Kim at Suheung Capsule

RE: Revision Notice No. 2018-12 - Standard and Specification of Health Functional Foods

To Whom It May Concern:

The Global Organization for EPA and DHA Omega-3s (GOED) is an international trade association of processors, refiners, manufacturers, distributors, marketers, retailers and supporters of products containing eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). GOED works with regulators and scientific groups to ensure consumers have access to high quality EPA and DHA products. Recently, GOED learned that the revision to the Standard and Specification of Health Functional Foods includes, for EPA- and DHA-containing fats and oils, an acid value limit of not more than 3.0 mg KOH/g (5.0 for products containing beeswax or lecithin) and a peroxide value limit of not more than 5.0 meq/kg. GOED is concerned that these limits may have the unintended consequence of restricting high-quality mixed oils from being marketed.

GOED brings to your attention two relevant documents for this discussion.

- 1) The [GOED Voluntary Monograph](#) has served as the industry standard for quality since 2002. The 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 an acid value limit of 3.0 mg KOH/g was included as a quality parameter in previous versions of the monograph, it is no longer included since the end of 2015. There are different factors that can contribute to the acid value and because there are now so many different types of EPA/DHA products, a single acid value limit can no longer be applied.

Your peroxide value limit of not more than 5.0 meq/kg matches the GOED Voluntary Monograph limit, but the addition of other oils that may have naturally higher peroxide values makes it unrealistic to expect a blended oil that includes an EPA- and/or DHA-containing oil to remain under that level.

- 2) In 2017, the [Codex Standard for Fish Oils](#) was adopted. The acid value was set at ≤ 3 mg KOH/g, with a higher value (≤ 45 mg KOH/g) allowed for high phospholipid oils like krill oil. The peroxide value limit was set at ≤ 5 meq/kg for all fish oils.



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In consideration of the GOED Voluntary Monograph and the Codex Standard for Fish Oils, GOED provides the following recommendations:

- 1) Peroxide Value: For EPA- and DHA-only-containing oils, without the addition of other oils, set a peroxide value limit of ≤ 5 meq/kg. For blends, allow flexibility depending upon what other oils are added to EPA- and DHA-containing oils. Canada has done this successfully. See the [Quality of Natural Health Products Guide](#), which provides acceptable limits for oxidative stability in marine oils, but acknowledges that “limits are appropriate for the raw materials, but may not be appropriate for the finished product if non-medicinal ingredients interfere with the testing.” In this case, it wouldn’t necessarily be non-medicinal ingredients interfering with the testing, but non-marine oils with naturally higher peroxide values leading to overall increased peroxide values.
- 2) Acid Value: For EPA- and DHA-only containing oils, without the addition of other oils, either delete the acid value or use the limits included in the Codex Standard for Fish Oils. For blends, allow flexibility depending upon the mixture of oils and the limits that apply to the individual ingredients.

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,

A handwritten signature in blue ink, appearing to read 'Harry B. Rice'.

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

A handwritten signature in black ink, appearing to read 'Gerard Bannenberg'.

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