



GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3S

29 January 2024

Natural and Non-prescription Health Products Directorate (NNHPD) Consultation
Health Canada, Government of Canada
nnhpd.consultation-dpsnso@hc-sc.gc.ca

RE: Comments Regarding Proposed Changes to Fish Oil Monograph

To Whom It May Concern:

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 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.

GOED appreciates the opportunity to provide the Natural and Non-prescription Health Products Directorate (NNHPD) of Health Canada with comments on the proposed changes to the Fish Oil Monograph.

On 9 November 2023, GOED sent an email to Health Canada (nnhpd.consultation-dpsnso@hc-sc.gc.ca) seeking clarification on whether concentrated omega-3 oil from fish oil, referred to hereafter as ‘concentrates,’ remained within scope of the fish oil monograph and on 22 November, you confirmed that concentrates remained in scope and for clarification, you proposed further changes to the Fish Oil Monograph. A copy of the email exchange is attached for your reference.

Since GOED has members who have been granted product licenses for their concentrates based on the Fish Oil Monograph, it was good to receive confirmation that concentrates remain within scope. Given that the upper dosage ranges associated with the majority of the “Use(s) or Purpose(s)” would be unachievable without concentrates, it would not have made sense to exclude them.

As you know, concentrates with high levels of EPA and/or DHA can be produced from refined fish oils. These concentrates are in either ethyl ester or re-esterified triglyceride form and have always been considered to be within scope of the Fish Oil Monograph.

Unfortunately, your proposed further modifications inadvertently exclude concentrates. You proposed changing “This monograph only covers naturally occurring amounts of fatty acids in fish oil and would not cover fish oils that are concentrated or spiked” to “covers naturally occurring amounts of fatty acids.” In order to ensure there is no question in the future about the inclusion of concentrates in the fish oil monograph, GOED proposes changing the text to ***This monograph only covers naturally occurring amounts of fatty acids in triglyceride forms in fish oil and concentrated ethyl ester and re-esterified triglyceride forms from fish oil and would not cover fish oils that are***



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spiked. We believe the changes are self-explanatory, but should you not agree, please let us know so we can provide an explanation.

GOED has one last comment and it relates to Table 2, footnote 2 – “Adult maximum dose is supported by EFSA 2012.” While GOED agrees with referencing EFSA 2012, GOED recommends clarifying that the maximum daily dose is 5,000 mg EPA+DHA. In addition to EFSA 2012, we recommend referencing US FDA’s 19 June 2019 letter of enforcement discretion¹ in response to a health claim petition submitted by GOED. In the letter, the Agency refers to an updated safety review with the conclusion “..., we conclude that dietary supplements that provide no more than 5 g/day EPA and DHA when used as recommended or suggested in their labeling are safe...”

GOED appreciates your consideration of our comments.

Sincerely,

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

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

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

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

¹ <https://www.fda.gov/media/128043/download?attachment>



Harry Rice <harry@goedomega3.com>

Re: Consultation on Updated Monographs

1 message

Harry Rice <harry@goedomega3.com>

Tue, Nov 28, 2023 at 9:30 AM

To: "NNHPD Consultation / DPSNSO (HC/SC)" <nnhpd.consultation-dpsnso@hc-sc.gc.ca>

Bcc: 22454452@bcc.hubspot.com

Thank you for the follow-up and my apologies for the delayed response. I am just catching up after the Thanksgiving holiday in the United States.

Regards,
Harry

On Wed, Nov 22, 2023 at 2:26 PM NNHPD Consultation / DPSNSO (HC/SC) <nnhpd.consultation-dpsnso@hc-sc.gc.ca> wrote:

Good afternoon Harry,

Thank you for your question. We agree that this information is unclear. As we would like to provide more flexibility and as many licensed fish oils are in fact concentrated, we will remove the term "concentrated" from the introductory statement and revise it to : "This monograph only covers naturally occurring amounts of fatty acids in fish oil and would not cover fish oils that are spiked".

Best regards,

Natural and Non-prescription Health Products Directorate Consultation

Health Canada, Government of Canada

nnhpd.consultation-dpsnso@hc-sc.gc.ca

Direction des Produits de santé naturels et sans ordonnance consultation

Santé Canada, Gouvernement du Canada

nnhpd.consultation-dpsnso@hc-sc.gc.ca

From: NNHPD Consultation / DPSNSO (HC/SC)
Sent: Tuesday, November 21, 2023 2:31 PM
To: 'Harry Rice' <harry@goedomega3.com>
Subject: RE: Consultation on Updated Monographs

Good afternoon Harry,

We apologize for the delay in response. Your message was shared with our monographs team for more information and we will get back to you as soon as able.

Best regards,

Natural and Non-prescription Health Products Directorate Consultation

Health Canada, Government of Canada

nnhpd.consultation-dpsnso@hc-sc.gc.ca

Direction des Produits de santé naturels et sans ordonnance consultation

Santé Canada, Gouvernement du Canada

nnhpd.consultation-dpsnso@hc-sc.gc.ca

From: Harry Rice <harry@goedomega3.com>

Sent: Monday, November 20, 2023 3:38 PM

To: NNHPD Consultation / DPSNSO (HC/SC) <nnhpd.consultation-dpsnso@hc-sc.gc.ca>

Subject: Re: Consultation on Updated Monographs

Hi,

I am resending the below email with the hope of gaining some clarification in advance of the December 1 consultation deadline. Thank you.

Regards,

Harry

On Thu, Nov 9, 2023 at 3:30 PM Harry Rice <harry@goedomega3.com> wrote:

Hi,

I work for GOED, the Global Organization for EPA and DHA Omega-3s, and we represent the worldwide EPA and DHA omega-3 industry. We plan to submit comments regarding the updated fish oil monograph, but I have a question that if you can answer would help me tailor our comments.

It appears that text may have been added to the fish oil monograph to exclude concentrated omega-3 oils from fish oil. If that was the purpose of the text, there is other added text that is contradictory.

The first text in question reads as follows, "This monograph only covers naturally occurring amounts of fatty acids in fish oil and would not cover fish oils that are concentrated or spiked." This contradicts information found as a footnote to Table 1, which reads, "Includes fish oil in its natural and/or triglyceride/triacylglycerol form and/or esterified form."

The reason the information is contradictory is that esterified forms of omega-3s from fish oil are considered concentrated.

If possible, it would be great if you can clarify the purpose of the text additions so that I can tailor GOED's comments and not have to address different scenarios (concentrates included versus excluded).

Thank you!

Regards,

Harry

Harry B. Rice, Ph.D.
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[Redacted]

On Thu, Nov 9, 2023 at 6:54 AM NNHPD Consultation / DPSNSO (HC/SC) <nnhpd.consultation-dpsns@hc-sc.gc.ca> wrote:

Good morning Harry,

I have attached the original email that went out to license holders, you can access the monographs using the links in the email

Thank you,

Natural and Non-prescription Health Products Directorate Consultation

Health Canada, Government of Canada

nnhpd.consultation-dpsnso@hc-sc.gc.ca

Direction des Produits de santé naturels et sans ordonnance consultation

Santé Canada, Gouvernement du Canada

nnhpd.consultation-dpsnso@hc-sc.gc.ca

From: Harry Rice <harry@goedomega3.com>

Sent: Wednesday, November 8, 2023 5:13 PM

To: NNHPD Consultation / DPSNSO (HC/SC) <nnhpd.consultation-dpsnso@hc-sc.gc.ca>

Subject: Consultation on Updated Monographs

Hi,

I understand the NNHPD has updated 28 monographs and launched a consultation to end December 1, 2023. Unfortunately, I have not been able to locate anything on the website. Can you please provide a link or provide additional information? Thank you!

Regards,

Harry