GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3S

April 4, 2019

Ms. Michelle Arsenault
Advisory Committee Specialist
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Ave. SW, Room 2642-S, Mail Stop 0268
Washington, DC 20250-0268
Submitted electronically at www.regulations.gov

RE: Docket ID: AMS-NOP-18-0071, National Organic Standards Board (NOSB) meeting April 2019, Fish Oil

Dear Ms. Arsenault:

GOED represents the worldwide industry for eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), the primary long-chain omega-3 fatty acids found in fish oil. Our membership is built on a quality standard unparalleled in the market and our mission is to increase consumption of EPA and DHA omega-3s, because of its wide range of well-known health benefits, and to ensure that our members produce quality products that consumers can trust. GOED understands that the National Organic Standards Board (NOSB), at its upcoming public meeting (April 24-26, 2019), will be discussing fish oil as part of the 2021 Sunset Review. In anticipation of the meeting, GOED appreciates the opportunity to provide information to the NOSB in an effort to facilitate its review of fish oil against the criteria in the Organic Foods Production Act (*7 U.S.C. 6518(m)*) and the USDA organic regulations (*7 CFR §205.6000*).

GOED continues to support the inclusion of fish oil in *7 CFR §205.606*, nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic." Consumers who prefer organic products should have access to products made with non-organically produced fish oil, since organic fish oil does not currently exist. Because the National Organic Program (NOP) does not have production standards for aquaculture, organic fish (and thus fish oil) cannot be commercially available as organic.

GOED will begin by providing some thoughts on sustainability, which, historically, seems to be the most contentious issue regarding the inclusion of fish oil in *7 CFR §205.606*. GOED will then provide the additional information requested by the Handling Subcommittee (HS) as outlined in the NOSB April 2019 Proposals and Discussion Documents. Finally, GOED will provide comments on the March 5, 2015 Technical Evaluation Report (TR) for Fish Oil.

Sustainability

GOED believes that protecting our oceans and natural resources is paramount. Maintaining our oceans is not only good environmental stewardship, but also ensures sustainable growth for the omega-3 industry as a whole. Fortunately, most of the fisheries from which fish oils are sourced

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have either been certified— or are currently pursuing certification—by the Marine Stewardship Council[1] (MSC). Other fisheries are certified by Friend of the Sea[2], another respected certifying group.

While GOED supports sustainable fishing practices, it's important to note that there is no fish species in the world that is caught primarily for fish oil production. Fish oil is always a value-added byproduct of fish meal or seafood production because the protein's value is much greater than that of the oil. As an illustration, in 2015, Peru, the largest fish meal and fish oil producer in the world, produced 858,000 tons of fish meal and 95,000 tons of fish oil, but the price per ton for each was about the same, making the fish meal about nine times more valuable than the fish oil.

In advance of the publication of the Dietary Guidelines for Americans 2015-2020, the 2015 Dietary Guidelines Advisory Committee (DGAC) dedicated significant resources to better understanding sustainability as it pertains to meeting Dietary Guidelines recommendations for consumption of at least eight ounces of seafood per week. With respect to sustainability, the Scientific Report of the 2015 Dietary Guidelines Advisory Committee[3] provided the following conclusion, "The DGAC concurs with the FAO report [State of World Fisheries and Agriculture] that consistent evidence demonstrates that capture fisheries increasingly managed in a sustainable way have remained stable over several decades. However, on average, capture fisheries are fully exploited and their continuing productivity relies on careful management to avoid overexploitation and long-term collapse." The DGAC rated this evidence as strong.

Contrary to popular belief, concluding that the capture fisheries are fully exploited is not negative. While the word exploit has a negative connotation for many, in describing the state of fisheries, exploit is not considered negative until we talk about being overexploited. FAO defines fully exploited as "The fishery is operating at or close to an optimal yield level, with no expected room for further expansion.[4]"

Additional information requested by Subcommittee

1. **Is there a mandatory standard for fish oil purity with limits on contaminants, dioxins and PCB's for example? How is purity assessed?**

In the United States, there is no mandatory standard for fish oil with limits on contaminants like dioxins and PCBs; however, GOED maintains a Voluntary Monograph with limits on contaminants based on some of the strictest global regulations. While the monograph is voluntary, it is mandatory for GOED members which means that all major fish oil manufacturers are complying with the limits of the Monograph. The most up-to-date version of the Voluntary Monograph can be found on

[1] https://www.msc.org/
[2] https://friendofthesea.org/
[3] https://health.gov/dietaryguidelines/2015-scientific-report/PDFs/Scientific-Report-of-the-2015-Dietary-Guidelines-Advisory-Committee.pdf
[4] http://www.fao.org/newsroom/common/ecg/1000505/en/stocks.pdf

the GOED website at https://goedomega3.com/storage/app/media/Governance%20docs/goed-monograph-2019-03-01-r.pdf. Below are the contaminant limits listed in the Monograph.

- PCBs: Maximum 0.09 mg/kg
- PCDDs and PCDFs: Maximum 1.75 pg WHO-PCDD/F-TEQ/g
- Dioxin-like PCBs: Maximum 3 pg WHO-TEQ/g
- Total Dioxins, Furans and dioxin-like PCBs: Maximum 3 pg WHO-TEQ/g
- Lead (Pb): Less than 0.05 mg/kg
- Cadmium (Cd): Less than 0.1 mg/kg
- Mercury (Hg): Less than 0.1 mg/kg
- In-organic Arsenic (As): Less than 0.1 mg/kg

2. How is the industry controlling for the risk of contaminants such as heavy metals and PCBs?

See answer to #1. In addition, GOED executes a randomized testing program to help ensure that its members are complying with the limits of the Monograph.

3. Is the Voluntary Standard from the Council of Responsible Nutrition (CRN) for contaminant limits still in effect?

The Council for Responsible Nutrition (CRN) Voluntary Monograph is now the GOED Voluntary Monograph. The Voluntary Monograph was originally created by the CRN Omega-3 Working Group. In 2007, the working group was spun off to form its own trade association known as GOED. Thus said, CRN's Voluntary Monograph is no longer in effect. The Voluntary Monograph is maintained and revised as necessary by GOED. The most up-to-date version can be found on the GOED website at https://goedomega3.com/storage/app/media/Governance%20docs/goed-monograph-2019-03-01-r.pdf.

4. How can the annotation be modified to control for the noted conservation concern?

Since the concern is that fish from overexploited fisheries are used to make fish oil, GOED suggests the following annotation (modification underlined): "Fish oil (Fatty acid CAS #'s: 10417-94-4, and 25167-62-8)—stabilized with organic ingredients or only with ingredients on the National List and processed only from fish originating from fisheries that are not classified as overexploited according to FAO guidelines."

Fish Oil Technical Evaluation Report

GOED is very concerned about the quality of the March 5, 2015 TR for Fish Oil compiled by ICF International and being relied upon by the HS. We wish to call to the Subcommittee's attention several statements from the TR that are quoted in the Subcommittee's document, but where the TR was demonstrably wrong or misleading. We will list those statements first. Then, we will identify

numerous other statements made in the TR that were not specifically cited by the Subcommittee but are also mistaken. Taken as a whole, these inaccuracies in the TR demonstrate a gross neglect for detail and a fundamental misunderstanding of many aspects of the topic (i.e. fish oil) that the TR was expected to cover.

First, the Subcommittee said, citing the TR lines 283-284, that fish oil "is produced from fish by-products or from fish that are caught specifically for the purpose of making fish oil."

TR lines 283-284: “Fish oil is produced from fish byproducts or from fish that are caught specifically for the purpose of making fish oil (Kim and Venkatesan, 2014).”
Comment: There is no fish species in the world that is caught primarily for fish oil production. Fish oil is a value-added byproduct of fish meal or seafood production because the protein’s value is much greater than that of the oil. In 2015, Peru, the largest fish oil producer in the world, produced 858,000 tons of fishmeal and 95,000 tons of fish oil, but the price per ton for each was about the same, making the fishmeal about nine times more valuable than the fish oil.

Second, the Subcommittee said, citing the TR lines 75-76, that whales are a source of fish oil.

TR line 75: “whale”
Comment: Whales are an endangered species and are not used to make whale oil.

TR line 385: “…whale blubber…”
Comment: As mentioned for line 75, whales are an endangered species and are not used to make whale oil.

Third, the Subcommittee said, citing the TR lines 489-494, that "health risks from fish consumption" may "outweigh the benefit of omega-3 fatty acids from fish oil."

TR lines 489-494: “There are some health risks from the consumption of fish that may outweigh the benefit of omega-3 fatty acids from fish oil. For example, women who are pregnant or may become pregnant, nursing mothers, and young children should follow U.S. EPA/FDA-recommended fish consumption levels due to the risk of exposure to mercury and methylmercury (Gebauer et al., 2006; Harris, 2004; Kidd, 2013; Mayo Clinic, 2013; Ruxton et al., 2004). The U.S. EPA/FDA provides recommendations for fish consumption for children and women of child-bearing age.”
Comment: This is a misinterpretation. GOED refers you to “A Quantitative Assessment of the Net Effects on Fetal Neurodevelopment from Eating Commercial Fish (As Measured by IQ and also by Early Age Verbal Development in Children)[5], which concludes that the benefits of fish consumption outweigh any risks.

Fourth, the Subcommittee cited a study of 31 fish oil supplements that found "every product contained measurable amounts of mercury, with an average concentration of 2.9 parts per billion

[5] http://www.fda.gov/downloads/Food/FoodborneIllnessContaminants/Metals/UCM396785.pdf

(ppb) across all brands." The Subcommittee did not cite TR lines 403-408 as its source, but this identical language is found in the TR at lines 403-408.

TR lines 403-408: "A laboratory analysis of 31 fish oil supplements found that every product contained measurable amounts of mercury, with an average concentration of 2.9 parts per billion (ppb) across all brands (LabDoor, 2014). The highest level of mercury recorded in the supplements was 6 ppb (LabDoor, 2014). The FDA action level for methylmercury in fish is 1 part per million (ppm) (U.S. FDA, 2011). The Global Organization for EPA and DHA Omega-3 (GOED) sets voluntary standards for fish oil. GOED recommends a maximum value of 0.1 mg/kg (i.e., 0.1 ppm or 100 ppb) mercury in fish oil."
Comment: Despite the negative tone, it's important to understand that none of the tested products exceeded the GOED Voluntary Monograph, which is considered the global benchmark for quality, limit for mercury content. In fact, the highest results were in products that contained levels of mercury 94% lower than the GOED Voluntary Monograph limit.

Fifth, the Subcommittee stated that an analysis "of 13 over-the-counter children's fish oil dietary supplements" showed that "every supplement contained PCBs..." The Subcommittee did not cite TR lines 413-415 as its source, but this identical language is found in the TR at lines 413-415.

TR lines 413-415: "An analysis of 13 over-the-counter children's fish oil dietary supplements showed that every supplement contained PCBs, with a mean concentration of 9 (± 8) ppb (Ashley et al., 2013)."
Comment: After reviewing the full reference [Ashley JT Ward JS Anderson CS Schafer MW Zaoudeh L Horwitz RJ Velinsky DJ (2013). Children's daily exposure to polychlorinated biphenyls from dietary supplements containing fish oils. Food Addit Contam Part A Chem Anal Control Expo Risk Assess. 30:506-14], which wasn't cited in full in the TR, it's important to put the presence of PCBs into proper context. As mentioned previously, GOED's Voluntary Monograph serves as the industry benchmark and includes maximum limits for certain contaminants, including PCBs. For PCBs, GOED's maximum limit is set at 90 ppb. In the article cited by the TR, the product testing with the highest PCB levels came in at 50 ppb, a level lower than the 90 ppb included in GOED's Voluntary Monograph which is based on the level established by California Proposition 65.

Below is the list of other statements made in the TR that were not specifically cited by the Subcommittee but considered by GOED to be incorrect and/or misleading. While the following list is extensive, it should not be considered comprehensive.

TR lines 2-5: "Chemical Names: Two omega-3 fatty acid components of fish oil: eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA)"
Comment: While EPA and DHA are the primary omega-3 fatty acids in fish oil, they are not the only ones. As noted in line 59-60, "ALA, SDA and DPA are also present." Although ARA is mentioned, it is an omega-6 fatty acid.

TR line 11: "Trade Names: None"
Comment: While we agree that trade names should not be listed, "None" is not accurate, since there are branded fish oils on the market.

TR lines 55-58: "Purified fish oil contains only the fatty acids naturally present in fish although oils used in pharmaceutical applications are usually formulated with antioxidants such as tocopherols and vitamin E and then packaged in a protective capsule (usually made of gelatin) to protect the oils from oxidation (Rizliya and Mendis, 2014)."
Comment: The majority of fish oil, not just that used in pharmaceutical applications, is stabilized with antioxidants.

TR lines 59-61: "Generally, fish oil contains the following omega-3 fatty acids: EPA, DHA, ALA, stearidonic acid, docosapentaenoic acid (DPA), and arachidonic acid. The omega-3 LC-PUFAs in fish oil are mostly EPA and DHA with some DPA (NLM, 2014; Pike and Jackson, 2010)."
Comment: Arachidonic acid is an omega-6, not an omega-3, fatty acid. These two sentences have similar information, but the fatty acids listed in each sentence don't completely overlap, leaving the reader to wonder which omega-3 fatty acids are in fish oil, particularly since arachidonic acid, an omega-6 fatty acid, is listed.

TR lines 142-144: "A recent systematic review and meta-analysis, however, indicated that omega-3 fatty acid supplementation was not associated with lower cardiovascular risks (Rizos et al., 2012)."
Comment: While Rizos et al., 2012 did not demonstrate a benefit for CVD risk, they did demonstrate a statistically significant reduction in cardiac death, which is one of the most consistent benefits associated with EPA/DHA to date.

TR lines 144-145: "Another large, recent study reported that daily treatment with omega-3 fatty acids did not reduce cardiovascular mortality and morbidity (Roncaglioni et al., 2013)."
Comment: While it's true that this study didn't find that omega-3 fatty acids reduced cardiovascular mortality and morbidity, there were issues with the experimental design, including the primary efficacy endpoint being redefined after one year, because the event rate for the original primary efficacy endpoint (cumulative rate of death, nonfatal myocardial infarction, and nonfatal stroke) was lower than expected after one year. Many times, when an omega-3 study fails to detect a cardiovascular benefit, the reason(s) is associated with the experimental design. In 2014, GOED sponsored a workshop at the 11th Congress of the International Society for the Study of Fatty Acids and Lipids (ISSFAL) to address this issue. The proceedings were subsequently published.[6]

TR lines 151-153: "Data from 2010 indicated that more than 16 percent of wild-caught fish (approximately 15 million metric tons) were processed into fish meal and fish oil, with the majority used in feed for aquaculture (FAO/UN, 2012; Fry and Love, 2013)."
Comment: The reference associated with "FAO/UN, 2012" is the FAO's State of World Fisheries and Aquaculture 2012." Every two years, the FAO publishes a new "State of the World Fisheries

[6] https://www.plefa.com/article/S0952-3278(15)30013-2/pdf

and Aquaculture" report, which means that the authors of the TR failed to cite the most up-to-date FAO report, which would have been the 2014 report, since the TR was published in 2015.

TR lines 163-171:
Comment: While the GRAS Notices listed are correct, there is an error by omission because the following four GRAS Notices were not listed: GRN 102 (small planktivorous pelagic fish body oil (SPPFBO)), GRN 109 (tuna oil), GRN 146 (salmon oil) and GRN 379 (tuna oil). In addition, it's important to note that the safety of fish oil was recognized five years before the first fish oil GRAS Notification received a letter of no objection from the FDA. More specifically, menhaden oil was affirmed as Generally Recognized as Safe (GRAS) in 1997.[7]

TR lines 203-206: "Preventing oxidation of fish oil is critical because the lipid peroxides that are produced from oxidized fish oil, as well as their breakdown products, can be cytotoxic (toxic to cells) and lead to oxidative stress, cell damage, and potentially DNA damage (Moffat and McGill, 1993)."
Comment: This has never been demonstrated in humans, so the suggestion, without substantiation, does nothing more than perpetuate a misperception.

TR line 225: "U.S. FDA GRAS notices for fish oil date back to 2002."
Comment: While this is a true statement, menhaden oil was affirmed as Generally Recognized as Safe (GRAS) in 1997.[8]

TR lines 304-305: "Fish oil may be further processed by hardening, which is performed to further purify the oil (U.S. EPA, 1995)."
Comment: If "hardening" refers to hydrogenation or partial hydrogenation, it's important to note that hydrogenated fish oil is no longer manufactured and sold. In fact, the 2015 Final Determination Regarding Partially Hydrogenated Oils recognized that "…partially hydrogenated LEAR and menhaden oils are not currently widely used by the food industry.[9]" At the time the TR was published, the U.S. EPA reference[10] was 20 years old. Had the author(s) of this TR been familiar with fish oils, s/he/they would have known that hydrogenation is no longer used in the fish oil industry.

[7] https://www.govinfo.gov/content/pkg/FR-1997-06-05/pdf/97-14683.pdf
[8] http://www.fda.gov/ohrms/dockets/dockets/95s0316/95s-0316-rpt0354-058-Ref-F-FR-Rules-Regulations-1997-vol273.pdf
[9] https://www.govinfo.gov/content/pkg/FR-2015-06-17/pdf/2015-14883.pdf
[10] https://nepis.epa.gov/Exe/ZyNET.exe/20005IRB.TXT?ZyActionD=ZyDocument&Client=EPA&Index=1995+Thru+1999&Docs=&Query=&Time=&EndTime=&SearchMethod=1&TocRestrict=n&Toc=&TocEntry=&QField=&QFieldYear=&QFieldMonth=&QFieldDay=&IntQFieldOp=0&ExtQFieldOp=0&XmlQuery=&File=D%3A%5Czyfiles%5CIndex%20Data%5C95thru99%5CTxt%5C00000002%5C20005IRB.txt&User=ANONYMOUS&Password=anonymous&SortMethod=h%7C-&MaximumDocuments=1&FuzzyDegree=0&ImageQuality=r75g8/r75g8/x150y150g16/i425&Display=hpfr&DefSeekPage=x&SearchBack=ZyActionL&Back=ZyActionS&BackDesc=Results%20page&MaximumPages=1&ZyEntry=1&SeekPage=x&ZyPURL#

TR lines 307-311: “Fish oil used for feed, aquaculture, supplements, or food applications is further purified using a carbon filter to reduce contaminants (e.g., dioxins/furans, polybrominated diphenyl ethers [PBDEs], polychlorinated biphenyl [PCBs], polycyclic aromatic hydrocarbons [PAHs]) that may be present in the oil (Rizliya and Mendis, 310 2014).”
Comment: While the aforementioned is true, molecular distillation is also used.

TR lines 348-350: “Some small amounts of DHA may be produced by metabolism of the essential fatty acid ALA (not present in fish oil) inside the human body, but this is not a significant source (Gebauer et al., 2006).”
Comment: While it’s true that the conversion of ALA to DHA is so inefficient that the amount of DHA produced is insignificant, it’s not clear why the statement indicates that there is no ALA present in fish oil since line 60 of the TR includes ALA as one of the fatty acids in fish oil. For the record, ALA may or may not be detectable in fish oil according to the Codex Standard for Fish Oils (CXS 329-2017).[11]

TR lines 375-376: “Table 4: FDA GRAS Status for Fish Oil Preparations”
Comment: See comment for lines 163-171.

TR lines 476-479: “However, a recent systematic review and meta-analysis of 20 studies involving a total of 68,680 patients showed that omega-3 PUFA supplementation is not associated with lower risk of mortality from cardiovascular diseases such as heart attack or stroke (Rizos et al., 2012).”
Comment: As mentioned for lines 142-144, Rizos et al., 2012 demonstrated a statistically significant reduction in cardiac death, which is one of the most consistent benefits associated with EPA/DHA to date.

TR lines 479-482: “A double-blind, placebo-controlled clinical trial of 12,513 individuals with multiple cardiovascular risk factors did not observe a reduction in cardiovascular morbidity and mortality following daily treatment with omega-3 fatty acids (including DHA and EPA) for an average of 5 years (Roncaglioni et al., 2013).”
Comment: As mentioned for lines 144-145, while it’s true that this study didn’t find that omega-3 fatty acids reduced cardiovascular mortality and morbidity, there were issues with the experimental design, including the primary efficacy endpoint being redefined after one year, because the event rate for the original primary efficacy endpoint (cumulative rate of death, nonfatal myocardial infarction, and nonfatal stroke) was lower than expected after one year. Many times, when an omega-3 study fails to detect a cardiovascular benefit, the reason(s) is associated with the experimental design. In 2014, GOED sponsored a workshop at the 11th Congress of the International Society for the Study of Fatty Acids and Lipids (ISSFAL) to address this issue. The proceedings were subsequently published.[12]

[11] http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCODEX%2BSTAN%2B329-2017%252FCXS_329e.pdf
[12] https://www.plefa.com/article/S0952-3278(15)30013-2/pdf

TR lines 496-498: "Omega-3 fatty acids may increase the risk of bleeding, especially when consumed at levels greater than 3 grams per day. People with bleeding disorders may experience an even greater risk of bleeding if they take fish oil supplements."
Comment: Two government reports have been published concerning the safety of EPA and DHA. Both reports concluded that there was insufficient data to establish a tolerable upper intake level (UL) which indicates an absence of safety concerns. The first report, from the Norwegian Scientific Committee for Food Safety (VKM), concluded that supplemental intakes of EPA+DHA at doses up to 6.9 g/day do not raise safety concerns.[13] The second report, from the European Food Safety Authority (EFSA), concluded that supplemental intakes of EPA+DHA at doses up to 5.0 g/day do not raise safety concerns.[14] Finally, in 2012, GOED commissioned a safety assessment on EPA and DHA from Spherix, Inc. The results are commensurate with those found in the reports from VKM and EFSA. GOED would be happy to share a copy with you.

TR lines 498-499: "People with fish allergies should also avoid omega-3 fatty acids derived from fish, as consumption could lead to skin rash and general allergic response."
Comment: This is a theoretical risk that to the best of GOED's knowledge has never been reported in the scientific literature.

Concluding Remarks

GOED encourages the NOSB to retain fish oil on the list of nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic." After all, consumers should have the right to buy products labeled as "organic" and containing fish oil.

Thank you for the opportunity to submit comments. Should you have any questions, please do not hesitate to contact me via email at harry@goedomega3.com or telephone at 612-600-6499.

Sincerely,

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

[13]Norwegian Scientific Committee for Food Safety (VKM) (2011). Evaluation of negative and positive health effects of n-3 fatty acids as constituents of food supplements and fortified foods. Norwegian Scientific Committee for Food Safety. Available online at http://www.vkm.no/dav/c7a41adb79.pdf.
[14]EFSA Panel on Dietetic Products, Nutrition and Allergies (2012). Scientific Opinion related to the Tolerable Upper Intake Level of eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA) and docosapentaenoic acid (DPA). EFSA J 10(7):2815. Available online at http://www.efsa.europa.eu/en/efsajournal/doc/2815.pdf.