GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3S

Regulatory Affairs Committee Meeting Minutes

Date: 5 August 2025
Last Meeting: 24 June 2025
Next Meetings: 30 September 2025

PRESENT
GOED Staff:
Aldo Bernasconi
Gabriela Cortez
Alexandra Gautier
Chris Gearheart
Harry Rice
Kaitlin Roke
Ellen Schutt
Committee Members:
Maria Albornoz (Pesquera Diamante)
Shabnam Behnam (NOW)
Jeffrey Blume (NOW)
Daniel Bohlen (KD Pharma)
Paul Browner (dsm-firmenich; chair)
Irena Brustad (Vitux/Concordix)
Blair Cabot (dsm-firmenich)
Jonathan Cortes (Naturmega)
Olenka Espinoza (Copeinca)
Monika Kogler-Voigt (Fresenius Kabi)
Mikayla Ladimir (Pharmavite)
Nick Lekovic (NOW)
Abdou Lemseffer (Herbalife)
Trine Hagen Lie (Epax)
Jai Kumar Mishra (BASF)
Carlos Perez (Naturmega)
Pongtorn Pitakgosolpong (Thai Union)
Jorge Sepúlveda (Innocon S.A.)
Sirilak Suwanrangsi (Thai Union)
Irwin Weerts (Corbion)
Allison Wilkin (Nature's Way Canada)
June Yao (Nufarm)
Mo Youssefi (Nordic Naturals)

US – EPA/DHA Recommendation

5 August 2025 Initial Discussion

- Ellen: I was at the NBJ Summit last week and Calley Means (https://en.wikipedia.org/wiki/Calley_Means) spoke which resulted in a number of one-off discussions about the current US administration (Trump, RFK, Jr., etc...) and the potential to raise

awareness of EPA/DHA. Calley's sister, Casey Means, is the current nominee for Surgeon General. Calley gave a presentation talking about what the supplement industry could be doing to gain traction or to get nutrients to have more visibility in Washington, D.C. He said, you're not big pharma, you're not big food. There are other things the supplement industry needs to do and the administration is looking for small, quick wins. During his presentation, he mentioned Omega-3s at least three different times. Separately from that, he apparently had one-on-one conversations with a few GOED members and also with Loren Israelsen from the United Natural Products Alliance (UNPA), one of the broad supplement associations in the US and the conversation was specifically about EPA and DHA and what could be considered a win for EPA and DHA in the US. One of our members suggested to make it essential, but GOED doesn't necessarily believe that's the best way to get recognition. We believe we need to have a conversation with the interested bodies to try and figure out what could be a possible path forward for EPA and DHA. We also talked about DRIs and that there is supposed to be a DRI review at some point in the future, but it's not yet funded and with the laying off of a lot of people in government, how do we find that money and the people to do it? I mentioned this to Loren Israelsen and he said that seems like a logical path, but that's not something that's a quick win, which they want in 2025. I think this is potentially good news for our industry, but it's also risky, because we want to make sure that we're not grandfathered in or lumped in with other controversial topics or orders or things that are happening in Washington. I'm raising this to this committee, because I know that there are companies here that are also well connected in Washington, or maybe doing lobbying, or may have more intel on this than what I know. Harry and I are having a conversation later this afternoon to talk to UNPA and a few of our key members to discuss what might happen next.

- Paul: So, they're looking for some sort of a win before the midterms in the fall of 2026, so why does it have to happen in 2025?
- Ellen: It's not clear. While we think there's enough science to establish a DRI, not everyone agrees and if it's just forced through, then that may set us up for a challenge down the road.
- Paul: Did you get the sense that Calley was putting it out there in hopes that he would get some unsolicited feedback from industry on how to approach this or did you get the sense that there would be something that is already kind of cooking around this and that we may see something later this year come from RFK, Jr and HHS and it may not be just about omega-3s, rather nutrients in general?
- Ellen: There was a CEO dinner as part of the conference and he attended that dinner and had a lot of those interactions. So, I think he was interested in soliciting opinions or suggestions from the industry about what should be done and how it could be done. He's called a special government employee, which you can do for 120 days and I don't know exactly what day he's on, but he said he could or could not be here next week. Regardless, it seems like he's still an influential voice for RFK, Jr., but I do think he wanted information from our industry. There are also things going on, because separately, we've heard that the Dietary Guidelines are coming out any day now, and that they're going to be very different from what people expect. There was conversation around children and getting rid of red dyes, artificial sweeteners and ultra processed foods. So, a lot of it is focused on the children's market too. Of course, DHA plays a major role for infants, so is that a path we should be pursuing? There are definitely conversations going on more broadly than just Omega-3s.
- Paul: DHA and ARA were specifically called out in the request for information (RFI) associated with the infant formula review. I guess the status as of now, is that there's no plan at the moment if or how GOED should potentially tackle this, but it certainly sounds like promising information. What is the specific ask?

- Ellen: I think we need to have a unified message and GOED needs to know what we want and be able to tell them what we can give them.
- Harry: Part of the discussion this afternoon is going to be what's possible, because we can give them anything they want scientifically.
- Ellen: We want to do this in the most scientifically validated and unquestionable way we can. Should we start with pregnancy since it's a low-hanging fruit for us and would be considered a quick win for them?

Canada – Can Fish Oil Monograph Claims be Used with DHA-Only Products?

5 August 2025 Initial Discussion

- Harry: I was asked by a member if the claims ("Use(s) or Purpose(s)") associated with the Fish Oil Monograph, can be used for DHA only products (i.e. children's development claims.
- Harry: I could probably argue both ways, but given that it's a fish oil monograph, I'd say that those claims are specific to products with a combined EPA and DHA, not one or the other. On the other hand, that monograph does include concentrates, so you could have high EPA concentrates or high DHA concentrates from fish oil that fall under the fish oil monograph. If that's the case, then I could almost argue that primarily DHA-only or EPA-only products could use those claims, but perhaps it would be a little riskier.
- Blair: You can't blanketly say yes to all of them, because some of the specific claims require EPA.
- Allison: I think the way that the claims are worded that you do need both, but I do feel like if you had a high-DHA product, but had at least a minimum amount of EPA (e.g. 50 mg), that you could still use the claims. Also, I want to point out that there is a fixed oil monograph and that one includes EPA and DHA separated, so you can get DHA only claims from that monograph. The only limitation is that it doesn't cover children. It's for adults only.
- Paul: When you look at the claims, I think some common sense has to be applied. To have a pure DHA oil, especially for fish oil, is not realistic. There's going to be some EPA in there. If you want to make claims on DHA only, use your discretion based on the specific health outcome of the claim.
- Blair: I agree with that approach, but there are a couple of claims that define a ratio between EPA and DHA, so you would need both.
- Harry: When you submit your product license application (PLA) to Health Canada, do you have to indicate at that time what claims you're going to use or do you submit the PLA with the understanding that if the license is granted that you can use any of the claims in the monograph?
- Allison: I'm not in regulatory affairs, so I don't submit PLAs, but I think you do have to choose at the time the PLA is submitted. I know when the monographs are updated, you don't automatically get to use the new claims for your product(s) that was previously granted a license. On the license you receive from Health Canada, the claims you can use are listed.
- Mo (via email in advance of the meeting, but I didn't see until after): The fish oil monograph requires both EPA and DHA for children's development claims (up to the age of 12 years). There is also the Fixed Oils Monograph, however it is only for those 18 years and up. Schizochytrium oil is listed. You can see in Table 3 that DHA-only products cover only these claims:
  - Source of docosahexaenoic acid (DHA) for the maintenance of good health
  - Source of omega-3 fatty acid for the maintenance of good health
  - Source of an essential fatty acid for the maintenance of good health
  - Helps support/maintain eye health/function

- Helps support/maintain visual health/function

Canada – Organic

5 August 2025 Initial Discussion

- Harry: GOED sent a letter to the Canadian General Standards Board requesting the addition of DHA algal oil to CAN/CGSB-32.311-202X (Organic production systems - Permitted Substances Lists). The Permitted Substances List includes non-organic ingredients that can be used in organic food production.

GOED to CanadaGeneralStand

- Harry: While GOED submitted comments, I suspect we were two years too late. A request to add something to the Permitted Substances List requires the submission of a proposed amendment to the Permitted Substances Lists. I believe the time to submit a proposed amendment would be after a review has been initiated of the Canadian Organic Standards and a call for modifications has been announced. The 60-day public comment period that just ended (July 29) is specific to the two draft documents which are based on the comments/proposals submitted in response to the call for modifications from August 2023.

CAN-CGSB-32.310-2025EN-for-Public-Rev

CAN-CGSB-32.311-2025EN-for-Public-Rev

- Harry: Organic regulations are very niche, not to mention difficult to understand, and I (not a GOED position per se) consider the opportunity to be very limited. Historically, GOED does not follow the organic regulations in any country, except the United States, and we do that to make certain fish oil stays on the National List of non-organic ingredients permitted for inclusion in products labeled "organic." The concern is that if fish oil is ever removed from the list that the media may report that it was removed because fish oil is not sustainable.

EU – *Calanus finmarchicus* oil

- Commission Implementing Regulation (EU) 2025/1513 of 28 July 2025 amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use and the additional labelling requirements of the novel food *Calanus finmarchicus* oil

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Gaby: The European Commission has updated the conditions under which Calanus finmarchicus oil may be used.

- Previously:

(1) in Table 1 (Authorised novel foods), the entry for '*Calanus finmarchicus* oil' is replaced by the following:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
'***Calanus finmarchicus* oil**	*Specified food category*	*Maximum levels*	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'oil from *Calanus finmarchicus* (crustacean)'. 2. The labelling of food supplements containing *Calanus finmarchicus oil* shall bear a statement that those food supplements should not be consumed: a) if other food supplements containing astaxanthin esters are consumed on the same day. b) by infants and children younger than 3 years. c) by children younger than 14 years, if the ingredient contains ≥ 0,1 % astaxanthin.'	
	Food supplements as defined in Directive 2002/46/EC, excluding food supplements for infants and young children	1,0 g/day (< 0,1 % astaxanthin esters, resulting in < 1,0 mg astaxanthin per day) for the general population, excluding infants and young children 2,3 g/day (from 0,1 % to ≤ 0,25 % astaxanthin esters, resulting in ≤ 5,75 mg astaxanthin per day) for the general population older than 14 years of age		

- Now:

The Annex to Implementing Regulation (EU) 2017/2470 is amended as follows:

(1) in Table 1 (Authorised novel foods), the entry for '*Calanus finmarchicus* oil' is replaced by the following:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
'***Calanus finmarchicus* oil**	*Specified food category*	*Maximum levels*	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be "oil from *Calanus finmarchicus* (crustacean)". 2. The labelling of food supplements containing *Calanus finmarchicus* oil shall bear a statement that those food supplements should not be consumed: (a) if other food supplements containing astaxanthin esters are consumed on the same day; (b) by infants and children younger than 3 years / children under 10 years of age / children and adolescents under 14 years of age depending on the age groups the food supplement is intended for.'	
	Food supplements as defined in Directive 2002/46/EC, excluding food supplements for infants and young children	0,9 g/day (≤ 2,25 mg astaxanthin per day) for the general population under 10 years of age, excluding infants and young children 2,2 g/day (≤ 5,5 mg astaxanthin per day) for the general population between 10 to 14 years of age 3,1 g/day (≤7,75 mg astaxanthin per day) for the general population older than 14 years of age		

International Society for the Study of Fatty Acids and Lipids (ISSFAL) 16th Congress

- Harry: At the end of June, the ISSFAL Congress took place and GOED sponsored a symposium entitled "Translating Research into Global Recommendations." The recording of the symposium is available.
    - Current Landscape of EPA/DHA Intake Recommendations; Harry B. Rice, PhD; GOED
    - Evidentiary Requirements for Setting Dietary Reference Intake Values; Amanda MacFarlane, PhD; Health Canada

  - Case Study 1: The Impact of Atrial Fibrillation Risk on EPA/DHA Recommendations; Aldo Bernasconi, PhD; GOED
  - Case Study 2: Australian Pregnancy Care Guidelines: Making it Work Globally; Ecushla Linedale; BSc(Hons), Grad Dip Sc Comm, Grad Dip Psych, PhD; Director, Implementation and Translation, Omega-3 Project
  - Case Study 3: Securing Krill Oil Claims in Australia; Nils Hoem, PhD; Aker Biomarine
- Harry: The A-Fib paper GOED (i.e. Aldo Bernasconi) had been working on and was mentioned during the symposium has been accepted for publication in the peer-reviewed journal Value in Health. The pre-published proof, as well as the Pub Med link, are now available online. We expect the paper to be published in print in October. See lead story in 28 July 2025 GOED Current.
  - Aldo: One of the questions that has been jumping around for a long time is whether the Afib reported harms are more serious and outweigh the cardiovascular benefits of Omega-3 supplementation. This is an article that takes a very systematic view of that and analyzes the impact of atrial fibrillation on the cost effectiveness of the use of supplements for secondary prevention in the United States. The conclusion is, of course, that the benefits outweigh the risks, and they do so in a cost-effective way. For how to generalize this to other populations outside the US, at least secondary prevention, my feeling is that it is even more cost effective in other regions where the cost of health care is lower, but we're working on trying to figure that out.

India – Food Supplements

5 August 2025 Update

- Harry: At the recent Codex Committee on Contaminants in Food (CCCF), India reaffirmed its intention to pursue new international standards for food supplements and will submit a proposal for new work to the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) to be discussed at its next meeting in 2026 (date not yet announced). This proposal was originally presented at the last meeting of the Codex Alimentarius Commission (CAC), and at that time, CAC advised India to submit the new work proposal to CCNFSDU.

Codex – Rosemary Extracts

5 August 2025 Update

- The Joint FAO/WHO Expert Committee on Food Additives (JECFA) 100th meeting (Safety evaluation of certain food additives) was held last month and the Summary and Conclusions have been published. As anticipated, rosemary extract, which is sometimes used as an antioxidant in omega-3 oils, was discussed and an acceptable daily intake (ADI) of 0–0.6 mg/kg bodyweight (bw) (expressed as carnosic acid and carnosol) per day was established. This replaces the temporary ADI of 0–0.3 mg/kg bw per day. The establishment of an ADI for rosemary extract means that it is one step closer to being added to the General Standard for Food Additives (CXS 192-1995) for use in fish oils per the Standard for Fish Oils (CXS 329-2017). Rosemary extract will be discussed further at the next Codex Committee on Food Additives (CCFA) in April 2026.

- To read the minutes on this topic from past meetings, click here.

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US – New Dietary Ingredient Notifications

5 August 2025 Update

- See FDA Releases 2025 Human Foods Program Guidance Agenda
- Harry: The US Food and Drug Administration (FDA) has released its 2025 Human Foods Program Guidance Agenda, highlighting priorities for completion in 2025, including "New Dietary Ingredient Notifications and Related Issues: Identity, and Safety Information About the NDI: Guidance for Industry." This has been in the works for well over then years. What's not clear is whether or not the guidance document can be issued without revoking 10 regulations. The current administration has said that for every regulation that is adopted that 10 have to be removed from the books. This is a guidance document, so maybe that doesn't hold true.

- To read the minutes on this topic from past meetings, click here.

US – Federal Trade Commission (FTC) "Made in the USA"

5 August 2025 Update

- Harry: See 8 July 2025 press release – "Federal Trade Commission Warns Companies to Comply with "Made in USA" Requirements."
    - The FTC sent warning letters to four companies who claim their consumer goods are of US origin, reminding them to comply with the FTC's "Made in USA" requirements.
    - Additionally, the FTC sent letters to Amazon and Walmart regarding third-party sellers who appear to be making deceptive "Made in USA" claims about their products on those online marketplaces.
    - While none of the warning letters went to dietary supplement companies, the requirements are the same.
- Harry: This administration is very much about bringing manufacturing back to the United States as much as possible and so it makes sense that they're going to enforce the made in the U.S.A. claims requirements.
- Paul: What strikes me about this one is that FTC is going after retailers, not just the manufacturers. This really is a heads up.
- Harry: I wonder if this isn't a warning that the FTC plans to start financially penalizing companies.

- To read the minutes on this topic from past meetings, click here.

Codex – Standard for Microbial Omega-3 Oils

5 August 2025 Update

- Harry: The 3rd consultation should be posted this month. I've had some communication with the chair of the electronic working group about the oils that are included in the draft standard and he communicated that he may propose only including some of the oils in the standard and once the standard is adopted that other oils can be added, similar to what happened with calanus oil and the Standard for Fish Oils. His concern is that there isn't enough data to include something like Nannochloropsis oil. When we started working on the proposal, we were only going to propose a standard for Schizochytrium oils and then we decided to propose a broader standard in order to have

the ability to add additional oils in the future. I think we're in a good place, but I don't think we're going to get all of the oils we originally wanted.

- To read the minutes on this topic from past meetings, click here.

Brazil – Proposed Normative Instruction on Ingredient Specifications

5 August 2025 Update

- GOED submitted a letter to ANVISA on 30 July 2025

GOED to ANVISA_30July2025_

- To read the minutes on this topic from past meetings, click here.

EU – Mineral Oil Update (not discussed during the meeting)

5 August 2025 Update

- See lead story - GOED Submits Letter to European Commission Regarding Latest MOH Proposal – in 14 July 2025 GOED Current.
- See 2nd story under Highlights in 28 July 2025 GOED Current

- To read the minutes on this topic from past meetings, click here.

EU – EFSA's Reassessment of the Safe Level of Intake of DHA (not discussed during the meeting)

5 August 2025 Update

- No update to provide.

- To read the minutes on this topic from past meetings, click here.

US – Infant Formula Ingredient Review – Operation Stork Speed

5 August 2025 Update

- No update to provide.
- Due date is 11 September 2025 and GOED plans to submit comments.

- To read the minutes on this topic from past meetings, click here.

ALL OTHER BUSINESS

GB Standard for Nutrition Supplement Foods for the Elderly

- On August 1, 2025, the China National Health Commission (NHC) released a draft national food safety standard for Nutrition Supplement Foods for the Elderly and EPA+DHA is listed as optional at 200-250 mg/day. This means that if a source of EPA and DHA is added, the product should contain 200-250 mg EPA+DHA. While stakeholders are invited to submit comments by 26 September 2025, GOED does not plan to do so. If any members feel strongly that GOED should submit comments, please contact Harry Rice to discuss.

Public consultation on GB 14880-xxxx Standard for the Use of Nutritional Fortification Substances in Foods

- The China National Health Commission (NHC) announced a public consultation on GB 14880-xxxx Standard for the Use of Nutritional Fortification Substances in Foods. The revised standard will replace GB 14880-2012, which already included DHA, but it reflects a significant update in both technical content and structural design. More specifically, the draft introduces more precise terminology that reflects China's dual-track approach to food fortification, including definitions for "population-based food fortification" and "voluntary food fortification." The food categories for voluntary fortification of DHA can be found in Table B.2. The last update to GB 14880 relevant to DHA was the amendment announced on 19 January 2023 by the China National Center for Food Safety Risk Assessment (CFSA), which adjusted the fortification amount of DHA from a percentage to a specific usage.

NOT ON AGENDA AND NOT DISCUSSED

Ireland – Novel Foods

- Guidance for Preparing an Article 4 Request to Ireland Under the Novel Food Regulation (EU) 2015/2283