GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3S

Regulatory Affairs Committee Meeting Minutes

Date: 24 June 2025
Last Meeting: 13 May 2025
Next Meetings: 5 August 2025

PRESENT
GOED Staff:
Gabriela Cortez
Harry Rice
Kaitlin Roke
Committee Members:
Helen Albans (Croda)
Jose Avalos (dsm-firmenich)
Boriana Bedjova (HuveNutra)
Shabnam Behnam (NOW)
Jeffrey Blume (NOW)
Daniel Bohlen (KD Pharma)
Paul Browner (dsm-firmenich; chair)
Mia Brastad (Zooca)
Olenka Espinoza (Copeinca)
Hywel Griffiths (Fermentalg)
Ingrid Jakobsen (Orkla)
Lisa Johnson (Mara Renewables)
Mikayla Ladimir (Pharmavite)
Abdou Lemseffer (Herbalife)
Trine Hagen Lie (Epax)
Jon O'Farrell (Vivo Brands)
Stephane Pasteau (Cargill)
Pongtorn Pitakgosolpong (Thai Union)
Natalia Sánchez (Innovaoleo S.L.U.)
Carlos Sepúlveda (Innocon S.A.)
Jorge Sepúlveda (Innocon S.A.)
Sirilak Suwanrangsi (Thai Union)
Bill Turney (Kerry)
Irwin Weerts (Corbion)
Allison Wilkin (Nature's Way Canada)
Guowen Yang (Kinomega)

US – Infant Formula Ingredient Review – Operation Stork Speed
24 June 2025 Update

- See story under "Regulations & Certifications" in the 19 May 2025 GOED Current.
- See second story in 9 June 2025 GOED Current
- Paul: Some of you may have seen that the FDA has recently announced an infant formula ingredient review – Operation Stork Speed. This is a routine review that hasn't been conducted since 1998. A

request for information (RFI) was published in the Federal Register and includes six "Issues for Consideration" including one of relevance to the omega-3 industry, which reads, "What other nutrients (e.g., docosahexaenoic acid and arachidonic acid) or specifications for nutrients (e.g., ratio of linoleic acid to alpha-linolenic acid), if any, should we consider adding to 21 CFR 107.100? Please explain your rationale." The due date is September 11.

- Harry: GOED plans to submit comments. We will likely comment on ARA briefly since it is used with DHA. The exception is the EU where DHA is mandatory, but ARA is not. There has been a request to include EPA and DPA in our comments. As far as I know, there is no scientific justification for the inclusion of either in infant formula and just because they are found in mothers' milk doesn't justify their inclusion in infant formula. What we will do is make a comment that all scientifically justified nutrients (i.e. Do they benefit the infant receiving the formula?), including fatty acids, found in the milk of lactating women should be considered for inclusion in infant formula. If anyone has comments that they would like us to consider for inclusion, please let us know by the end of July. We are likely to start drafting our comments once the comments to ANVISA are submitted and those are due 1 August. This is a unique opportunity to get DHA on the mandatory list of infant formula ingredients, particularly since there is no dietary reference intake (DRI) for DHA.

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

Brazil – Proposed Normative Instruction on Ingredient Specifications

24 June 2025 Update

- Gaby: Consultation deadline has been extended until 1 August 2025
- Gaby: Following Vitafoods Europe, our Codex consultant, David Pineda, who also does work in South America, shared with us that ANVISA has a tool that allows users to search for approved novel foods/ingredients. After reviewing the tool, we asked David some follow-up questions about the open consultation. The questions and answers are worth sharing since they provide guidance that we should consider when writing our comments to ANVISA.
  - Questions (GOED):
    1) What is the association between the ingredients found in ANVISA's tool and the ingredients found in the public consultation? We ask the question because some (but not all) of the ingredients found in the tool are included in the public consultation.
    2) Provided all of the ingredients found in ANVISA's tool are not supposed to be included in the public consultation, what's the rationale for the ingredients included in the public consultation? We want to make certain that our comments to ANVISA are reasonable and are not interpreted as us not understanding their regulatory system. We find it particularly odd that Annex II includes three oils from Schizochytrium, including two that reference the EU list of novel foods. The EU list of novel foods includes eight oils from Schizochytrium, so that means that only two of the eight Schizochytrium oils are included in Annex II. We are wondering if we should ask ANVISA for the others (or a subset of the others) to be included in Annex II?
    3) Can any company use the ingredients in Annex III provided they meet the specifications set by the listed company or is the use of the ingredient exclusive to the company associated with the ingredient?

- Answers (based on David's discussion with Rodrigo Martins de Vargas, Coordinator of Food Standards and Regulations of ANVISA)

1) & 2)

- He confirmed that the Public Consultation 1.324 was launched to provide stakeholders with the opportunity to send comments and suggestions on the proposed Normative Instruction that establishes the specifications of identity, purity and composition of ingredients authorised for use in food.
- I then raised the issue that not all ingredients in the proposed Normative Instruction are included in ANVISA's Tool of novel foods/ingredients. He explained that this was because they had not had time yet to include the most recently authorised novel ingredients not yet included in the Tool, something they still need to do, and confirmed that these ingredients have an ANVISA declaration approving their use in foods.
- He further indicated that the plan is to revise the Tool to include a specifications column for all novel foods/ingredients. He acknowledged that information on specifications is sometimes limited, based on input from novel food/ingredient applicants. In this regard, he encourages stakeholders to provide information to ensure the completeness of the information related to the specifications.
- Considering the above and in response to your question on Schizochytrium oils, it would indeed be appropriate to ask ANVISA for all Schizochytrium oils to be included in Annex II, for example.

3)

- ANVISA explained that the ingredients listed in Annex III were authorised by granting the applicant companies the right to use the ingredient exclusively for the company associated with the ingredient. Therefore, any other company that may want to use any of the listed ingredients is required to request authorisation to the company associated with the listed ingredient. Alternatively, companies may want to decide to go through the novel food/ingredients process to get their ingredient authorised with its own specifications. Please note as well that during the discussion the idea came up that stakeholders request that the proposed Normative Instruction includes a mechanism to request equivalence so that other companies can use similar ingredients.
- During my conversations with ANVISA, they expressed the importance of receiving comments with proposals and that they are very open to considering them. They are actually in the middle of a process of reorganising and structuring the regulation on new foods/ingredients, which they aim to complete within the next two years. Therefore, they are keen to receive comments with suggestions.

- Gaby: We're still assessing whether to ask for the inclusion of specific Schizochytrium oils that are particularly relevant to our industry or whether a generic usage listing could serve as an alternative. Please provide your feedback, which we will take into consideration.
- Harry: I think we need to provide sufficient comments and options so that if they don't like one option that perhaps they will like the other option. For example, for the Schizochytrium oils, only 2 of the 8 on the Union List are included in Annex II. We could possibly recommend the other 6 be included. Alternatively, we could recommend a generic entry be included so that all 8 would be acceptable.
- Hywel: I'm having a couple of conversations with companies producing algal oils to try and feed back into Gaby and yourself. I think the generic would possibly work. I've got one more

conversation to have, but I think, as you say, we provide that as plan A, and then go well, if not Plan A, then Plan B, which would be to give anyone who has a marketed oil the opportunity to play on a level playing field.

- Harry: ANVISA's tool is not clear to me in that if there is an omega-3 product in that tool that isn't included in the open consultation, should we ask for it to be included?
- Gaby: Yes. The tool is a little confusing, because of the name of the ingredients. I think that's also something that we might want to ask for further clarification about the defined ingredients.
- Harry: If they intended to include everything in the tool, why wouldn't the regulation just refer to the tool or the list gets updated on a regular basis based on the tool? Which takes precedent for regulatory purposes?
- Hywel: The tool appears to be a viewer for what was in place up until this new draft regulation was created.
- Harry: If you're selling product in Brazil, this is particularly important, so please review the consultation and let us know if you have comments.

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

Japan – Can an omega-3 rTG contain EEs?

24 June 2025 Original Discussion

- Harry: Recently, a member asked if an omega-3 rTG marketed/sold in Japan can contain omega-3 ethyl esters. During the 31 August 2021 committee meeting, we had a general discussion about the permissibility of ethyl esters being present in re-esterified triglycerides (rTGs), but Japan was not part of that discussion.
- Harry: There are omega-3 ethyl esters being sold in Japan, but there's no specific regulation authorizing their use in dietary supplements. What I've been told is that an ingredient which is used or specified as an active pharmaceutical ingredient (API) cannot be used as a dietary supplement ingredient unless it can be used as a food ingredient. Omega-3 EEs are not allowed to be used as a food ingredient in Japan; therefore, they cannot be used as a dietary supplement ingredient.
- Harry: The question for consideration is as follows: "For omega-3 rTGs being sold in Japan, is it acceptable for there to be a presence of omega-3 ethyl esters?
- Paul: I don't think I've ever seen any regulation answering the question about whether or not omega-3 rTGs can contain some amount of ethyl esters. I would say that the conversion to re-esterified triglycerides from ethyl esters is not 100% efficient, so there's going to be some ethyl esters remaining. I think it comes down to the risk assessment of knowing your process and how efficient it is. If you end up with a small amount of rTGs, I don't think it's going to be an issue.
- Hywel: I hesitate to give an opinion, because I know very little about how the Japanese would treat this, but I would agree that if reasonable efforts have been made to remove them given that they are an unavoidable process intermediate that it won't be an issue, but if your efforts have not been particularly stringent then you might run into issues.
- Jon: This issue didn't come up in the registration of my products in Japan.
- Harry: During the registration, did they look at your specifications or a CoA?
- Jon: Yes
- Harry: Did it show the presence of rTGs?
- Jon: Yes, at a small percentage, like 5%.

- Harry: I think 5% is what the European Pharmacopoeia has in their specifications.
- Paul: That's good information, because it's certainly evidence to say that they're not so concerned about it if you can demonstrate that your process is in control for the conversion.

Canada – DHA Schizochytrium Algal Oil Upper Limit of 2 Grams/Day

24 June 2025 Original Discussion

- From the Agenda: In Canada, there are two monographs that reference Schizochytrium Oil.
  - The Cognitive Function Products monograph indicates a daily dose for Schizochytrium oil of "DHA: 200-2,000 mg."
  - The Fixed Oil Products monograph indicates a daily dose for Schizochytrium oil of "DHA: 200-2,000 mg" and "Oil: up to 5 g and EPA and/or DHA as per Table 3*"
- Jon: I have a dilemma regarding the sale in Canada of a product with DHA from Schizochytrium oil. Health Canada uses monographs for licensing purposes to get this product into market as a finished product. I have a product in the market right now and I'm mandated by law to not exceed 2,000 mg of DHA from Schizochytrium oil. Over the last couple of years, I've been trying to come up with enough evidence to support going above 2,000 mg of DHA per serving and I've been roadblocked. I've provided a lot of different information to the government, including results from clinical trials, manufacturing information and evidence that it is safe. With the help of Kaitlin, I've exhausted the information from the CSD. I'm wondering if anyone from this group has information from a clinical study that might support going past 2,000 mg of DHA.
- Harry: For Clarification, it's 2,000 mg of DHA from Schizochytrium?
- Jon: Correct
- Hywel: With minimal EPA?
- Jon: Yes, ~1%. In the product, I'm using a 50% concentrate. I put in 4 grams, and I get 2 grams of DHA and that's my daily limit.
- Hywel: Seems to parallel what's going on in the EU.
- Jon: I could do a 1,000-2,000 person clinical study which would cost me tens of thousands of dollars to conduct. Upon the results of the clinical trial, as long as Health Canada recognized it, I would then be able to use it, but everybody in the industry would be able to use it as well. So, I was thinking that there might be an opportunity to do something collaboratively as a GOED function/group.
- Harry: It sounds like this is an efficacy issue and not a safety issue. Is that correct?
- Jon: Yes.
- Harry: OK, so it is different than the EU.
- Jon: No, it's not a safety issue, because it's generally recognized as safe.
- Harry: I think it depends on the country/region. The EU has asked EFSA to reevaluate the tolerable upper intake of DHA alone, because they want data to demonstrate that it's safe above one gram per day. We're going through the process of looking through the studies to see if there is supporting evidence to support the safety.
- Jon: There is supporting evidence to go up to 2,000 mg.
- Harry: Is that referenced in the monograph.
- Jon: It is referenced in the monograph, and I do have access to that information. I found it several times. It is out there up to 2,000 milligrams or 2 grams, but past 2 grams, I haven't been able to find it.

- Harry: Ok. If you could provide the references for up to 2 grams that would be helpful for the EU exercise that we're working on.
- Jon: OK
- Harry: As far as the > 2,000 mg for efficacy (i.e. cognition), off the top of my head, I don't know if there is interest in that. That may be something that Kaitlin can gauge during the science committee meeting, but it's probably something that you'll need to take up with the board, because it's a funding issue.
- Jon: I wasn't looking for funding. I was thinking more along the lines if companies wanted to go together.
- Harry: Let me talk to Ellen about that and maybe we can put something in the GOED Current. I think that's about the only way to approach funding unless you want to go to individual companies and ask about their interest.
- Jon: I have a call with Ellen on the 7th, so I can bring it up.

EU – Mineral Oil Update

24 June 2025 Update

- See 12 June 2025 News Alert - Latest and Final MOH Regulation Proposal Released by European Commission
- See 23 June 2025 GOED Current - Additional Mineral Oil Hydrocarbon EU Regulation Updates
- Harry: As mentioned in my 23 June email to the committee, GOED has prepared a draft letter that we are considering sending to the European Commission to seek clarification on some issues and make some suggestions to improve the draft regulation for mineral oil hydrocarbons. You can provide feedback during today's call or via email to me and Gerard (gerard@goedomega3.com) by the end of the day this Thursday, 26 June. If you are going to recommend the inclusion of a new point/argument not reflected in the letter, please support such point/argument with testing results and a short explanation.
    - Letter to EC June 2025 - DRAFT - v220
        - The letter addresses 6 issues (5 suggestions and 1 fyi)
            1) GOED recommends reinstating the category name as "Fish Oils and Oils from Other Marine Organisms, and Algae"
            2) GOED recommends not adopting a Maximum Level for crude unrefined EPA/DHA omega-3 oils because these oils need to be refined first
            3) GOED recommends creating a category for oils that are blends of oils from category 5.5.2.5 with vegetable oils
            4) GOED recommends including the handling of measurement uncertainty in SANTE PLAN 2023 2726 Rev.6
            5) GOED recommends European Commission guidance on the need for organizing a laboratory proficiency program for EPA/DHA omega-3 oils
            6) GOED recommends recognition of limitations and rising analytical testing costs for confirmatory analyses of EPA/DHA Omega-3 Oils because of the need to deal with inevitable matrix interference

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

EU – EFSA's Reassessment of the Safe Level of Intake of DHA

24 June 2025 Update

- Harry: The search has been completed and now the articles need to be scanned to determine which studies meet the inclusion criteria of providing greater than or equal to 1 gram DHA per day. Given that we didn't receive any feedback from EFSA regarding the presence of a minimal amount of EPA, we are including EPA studies as long as the EPA amount is no greater than 1/10 the amount of DHA. This is arbitrary. The articles will be scanned late July/August to come up with a list of relevant articles. After the list is compiled, we will determine how we are going to proceed. That is, we'll decide if we are going to just provide EFSA a list of articles or if we are also going to include any type of analysis.

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

US – Webinar on GRAS Process for Substances for Use in Human Food vs. Animal Feed

- Webinar on GRAS Process for Substances for Use in Human Food vs. Animal Feed

ALL OTHER BUSINESS

18th Session of the Codex Committee on Contaminants in Food (CCCF)

- On Sunday (22 June 2025), there was a keynote speech on "Exploring Mineral Oil Hydrocarbons – risks of MOH."
- During discussions on FAO-related matters, India reopened the question of how Codex should address food supplements. Referring to the FAO's new report on food safety in personalized nutrition, India called for global standards for supplements, noting the report as a useful reference. India first raised this issue at the Codex Alimentarius Commission and is expected to bring it forward again at the Nutrition Committee in 2026. This is a particularly interesting topic to be raised by India given there has been discussion within India to regulate nutraceuticals as medicinal products. This committee discussed this issue during the 12 March 2024 meeting.
    - The question/proposal was originally raised by India during CAC47.
        - CAC47 noted the proposal from India and the explanation of the Codex Secretariat that when a clear pathway existed for considering new work proposals, that pathway should be followed to ensure thorough technical review of the proposal. A Member noted the existing Guidelines for vitamin and mineral food supplements (CXG 55-2005) and that all new work proposals should fall within the statutory purpose of Codex. Conclusion 253. CAC47 invited India to submit the new work proposal to CCNFSDU through its established processes.