GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3S

Regulatory Affairs Committee Meeting Minutes

Date: 8 April 2025
Last Meeting: 25 February 2025
Next Meetings: 13 May 2025

PRESENT
GOED Staff:
Aldo Bernasconi
Gabriela Cortez
Chris Gearheart
Harry Rice
Kaitlin Roke
Ellen Schutt
Committee Members:
Helen Albans (Croda)
Boriana Bedjova (HuveNutra)
Shabnam Behnam (NOW)
Daniel Bohlen (KD Pharma)
Paul Browner (dsm-firmenich; chair)
Irena Brustad (Vitux/Concordix)
Barb Davis (Nufarm)
Olenka Espinoza (Copeinca)
Hywel Griffiths (Fermentalg)
Kirsten Humphreys (Bare Biology)
Ingrid Jakobsen (Orkla)
Oliver Kromer (Imperial OEL Import)
Abdou Lemseffer (Herbalife)
Jai Mishra (BASF)
Jon O'Farrell (Vivo Brands)
Jessica Rendall (Nestle)
Deyanira Roman (Aker Biomarine)
Michelle Stout (Amway)
Allison Wilkin (Nature's Way Canada)
Guowen Yang (Kinomega)
June Yao (Nufarm)
Mo Youssefi (Nordic Naturals)

US – Tariff Exemptions

- See 4 April 2025 News Alert
- Harry: On the exemption list are products related to dietary supplements. While there does not appear to be a formal process to request tariff exclusions, GOED may submit a written request (to whom it would be directed is unclear) for tariff exclusions related to the omega-3 industry. In anticipation of this activity, we're collecting tariff codes (for products coming from anywhere in the

world). In the United States, the code to export a product is not the same code that is used to import a product.

- Michelle: They could be the same, but often times the countries give them different codes. We saw that associated with the China facility registration issue.
- Harry: I think that's what has confused me over the years is that sometimes, but not always, they are aligned.
- Harry: The other thing is that the exemption codes in Annex II of the Executive Order are eight digits, but there are ten digit codes, so it's not clear to me if you need to use an eight or a ten digit code.
- Harry: After the call, I found "How to Read a U.S. HTS Code." "An HTS (harmonized tariff schedule) code can be 8-10 digits, depending on the country. The HS (harmonized system) code makes up the first 6 digits, while the importing country assigns the remaining 2-4 digits."

China – draft National Standard for Health Food Raw Material Catalog, Fish Oil

- See 31 March 2025 GOED Current
- Harry: China has released for consultation the Draft National Standard for Health Food Raw Material Fish Oil. Once finalized, this will formalize the dosage forms and technical requirements from the Health Food Raw Materials Catalogue/Positive List for Fish Oil that came into effect on 1 March 2021. By comparing the specifications that came into effect on 1 March 2021 to those in the draft National Standard, there are several differences, but only the specification that limits the EPA+DHA concentration to 70g/100g is of concern since GOED members are selling higher concentrations of fish oil in China. GOED is planning to submit comments by the 11 May 2025 deadline.
- I have received feedback from several members suggesting we focus on a daily upper limit as opposed to the maximum dosage concentration of 70%. If we do this, we would suggest a five-gram upper limit commensurate with the following:
    - Letter Responding to Health Claim Petition dated April 24, 2014: "Eicosapentaenoic Acid and Docosahexaenoic Acid and Reduction of Blood Pressure in the General Population" (June 19, 2019)
    - 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
- Hywel: I suspect this is being done to distinguish supplements from drugs and if that is the case then you would likely start to lose the battle at a concentration just before Lovaza (85%).
- Harry: That was my original thought, but I was informed that Lovaza isn't approved for use in China.
- Hywel: No, but I suspect whether it's approved or not, it's seen as the first pharmaceutical and is likely being used as a baseline.
- Ellen: Is there an approved upper limit in China?
- Michelle: There's a range for these products that can be through this notification system. So there is an upper.
- Aldo: I think the question may have been about the daily upper intake limit.
- Michelle: I'll pull up the DRIs.
- Harry: I think we can argue for 5 grams a day based on EFSA and the United States.

- Jon: For China, from what I understand is that you can have the higher potencies or the higher concentration limits as long as you're selling on the E-platform. As long as you are not going to Mainland China, you can sell anything above 70% and there's no regulatory requirement to register.
- Harry: So, the raw material catalog isn't relevant?
- Michelle: Not for cross-border since that's for personal consumption. There are limits (e.g. money) per person, but they're not held to the same standard of having to go through the blue hat registrations. They just need to meet the requirements of the countries from which they're being exported.
- Ellen: We've heard the same from a couple of our members that this is only impacting in China.
- Jon: Yes, at what I call brick and mortar stores. That's very different from E platforms.
- Harry: I don't know that that will necessarily change our approach or how we address this issue with the Chinese Government.
- Ellen: I wonder if there's a free trade argument that you're letting these other products be available on the market, but products that are manufactured locally are not.
- Michelle: You might want to be careful because that impacts a broader group of products, not just omega-3s.
- Harry: I would prefer not to address cross-border in our comments, because it could create unintended consequences. It is an impediment to free trade, which is a strong comment, but it is valid, particularly given there's no cap associated with the Codex Standard for Fish Oils. I don't know if that's a compelling argument for China not to adopt a concentration higher than 70%. Does anybody have an opinion on focusing on a product concentration limit versus a daily upper limit.
- Daniel: From KD Pharma's side, we like the daily recommendation approach.
- Paul: The daily recommendation would be much lower than what the upper limit would be.
- Michelle: I didn't find an upper limit. I found an AI for EPA/DHA, which is low.
- Paul: If we went with a recommended level, I think that would be counterproductive to what we're trying to do here.
- Daniel: For example, to address a daily upper limit, EFSA's 5 grams EPA+DHA.
- Paul: I think you just have to distinguish between what's a daily recommendation and a daily upper limit.
- Michelle: One thing to consider with regards to the national standard for the raw material, the levels are set on a different standard than for the fish oil use in that catalog. So, you could give the comments, but it's a different group. The national standards are being looked at by the National Health Commission (NHC), and that's the one that is updating them. SAMR is the one who sets the level in the finished product. This is just like the USP compendium of quality criteria. It's not what's in the finished good. For every product that goes through a notification, the raw material must follow a national standard. So, this is the national standard that's applied for use in the health foods.
- Harry: So, recommending that they set it as a 5-gram upper limit is irrelevant.
- Michelle: It's a different piece of regulation that does it. It's a whole catalog on fish oils.
- Harry: Well, I'm not interested in wasting words if they can't do anything with the recommendation.
- Michelle: The only thing I can think of is if you can make a safety argument that there's not a safety concern, because these are broadly used in these categories around the globe at higher concentrations.
- Harry: Perhaps we can address both concentration (Codex) and daily (EFSA, US) upper limit.
- Paul: What is the deadline?

- Harry: May 11.
- Paul: GOED will draft the letter and circulate it?
- Harry: I will do my best to circulate it in advance.
- Michelle: Harry, I have to go back on what I just said because I clicked on your link and it's not a national standard, it's the health food catalog where they put the technical standards in there so you could comment on the levels.
- Harry: I thought the draft national standard included the 70%.
- Michelle: The link you have is to the solicitation for what they call the health food raw material catalog. GBs are national standards. This is a standard from the Technical Committee for Special Foods. It is related to the health food, so I don't know if that changes the strategy. Maybe we can come up with some thoughts offline, but I still think it should focus on the safety.

EU – EFSA: Ask a Question

- See EFSA – Ask a Question
- Gaby: We want to highlight the "Ask a question" portal from EFSA. The service allows the user to ask EFSA questions about its work. It could help you access documents in EFSA's possession that are not posted or even documents that are posted, but difficult to find. The web form to submit a question is short and self-explanatory. Once the question is submitted, EFSA will send a confirmation email and get back to you within 15 working days. We have, however, received responses back much faster.

US – Food and Drug Administration (FDA) Review of Ingredients (Operation Stork Speed & Self GRAS)

- Infant Formula
  - See 18 March 2025 Press Release entitled "HHS, FDA Announce Operation Stork Speed to Expand Options for Safe, Reliable, and Nutritious Infant Formula for American Families."
  - Paul: We don't have a lot of information. For infant formula, it's not clear if both mandatory and optional ingredients will be reviewed. Recently, there's been an increased emphasis on heavy metal testing in infant formula which could have an impact on certain ingredient suppliers. Of course, they're encouraging companies to approach the FDA with any questions.
  - Harry: My concern is that the administration would overstep its authority. For example, in the unlikely event that RFK, Jr doesn't like DHA and doesn't think it should be in infant formula, could he just say no more DHA without a proper review?
- GRAS (self-affirmation)
  - See 10 March 2025 Press Release entitled "HHS Secretary Kennedy Directs FDA to Explore Rulemaking to Eliminate Pathway for Companies to Self-Affirm Food Ingredients Are Safe."
  - See Governmentally Recognized as Safe
  - Paul: Self GRAS is a legal pathway. My understanding is that the FDA doesn't have a lot of flexibility. If the self GRAS pathway should go away, it would be almost impossible for them to retroactively apply this. That is, ingredients that are currently self-affirmed would likely be grandfathered in. I think there's consensus that there's no capacity within the FDA

to retroactively review ingredients that are self-affirmed GRAS. Of course, given that there's no record of the GRAS determination, how do you grandfather those ingredients.

- Harry: I don't think it will be a huge issue for the omega-3 industry, but I think it could be an issue for the general dietary supplement industry. I think there are companies using the self GRAS route as opposed to filing New Dietary Ingredient Notifications. While I believe this is permitted based on past draft guidance from the FDA, guidance (particularly draft guidance) doesn't constitute a change in regulation(s). The benefit of this administration is that they seem to be pro-supplements.

US – State Bills to Ban Food Dyes and Additives

- From agenda: West Virginia House Bill 2354, passed on March 14, 2025 and signed into law on March 24, prohibits (as of January 1, 2028) the sale of foods and drugs containing, butylated hydroxyanisole (BHA), propylparaben, Red No. 3, Red No. 40, Yellow No. 5, Yellow No. 6, Blue No. 1, Blue No. 2, and Green No. 3. Similar bills are pending in other states.
- Gaby: These substances will be banned as of January 1, 2028. While I'd like to hear your thoughts, my interpretation of the state code is that dietary supplements would be regarded as food in West Virginia. In another chapter, it indicates that dietary supplements are any product other than tobacco intended to supplement the diet. It also defines drugs as other than food and food ingredients, dietary supplements or alcoholic beverages, so I interpreted that dietary supplements are not drugs in the state.
- Michelle: Other states have similar requirements that have been extended to disallowing immediately the use in school meal programs. In most cases, because of the federal law, dietary supplements are considered food, then supplements would apply.

Webinar – Foreign Trade Zones

- See 31 March 2025 GOED Current
- Harry: On Wednesday (9 April) GOED is hosting a webinar on foreign trade zones (FTZ). Daniel Mabey from UNPA is presenting and he is a wealth of information.
- Here is a link to access the webinar and slides on the GOED website.

Consensus Panel

8 April 2025 Update

Ellen: Late last year, we mentioned that we are putting together a scientific consensus panel to weigh in on an intake for EPA and DHA for healthy adults, with the goal of gaining a consensus and publishing in a peer reviewed journal to be able to use it for policy conversations, educating healthcare practitioners, possibly marketing and getting this on labels in various locations to have a consistent message about what EPA and DHA intake should be. A couple of weeks ago, the Board approved moving forward with this project and we are going to work with Nlumn (i.e. Josh Anthony), who GOED worked with previously on some diagnostics work. I think we have a solid plan to have a series of virtual meetings followed by an in-person meeting later this year. We have a list of experts that we are about to reach out to.

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

EU – EC Working Group on Novel Foods

8 April 2025 Update

- Harry: We have met internally and plan to do an updated search on DHA only studies, but the search has not yet begun.

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

Codex – Standard for Microbial Omega-3 Oils

8 April 2025 Update

- Harry: The second consultation closed on 31 March 2025. In addition to GOED's comments, four Codex Member Countries provided feedback, including: the EU, Malaysia, Canada and Brazil. Gerard and I are scheduled to speak to the chair of the working group on Thursday to discuss the comments received. The third draft Standard will be circulated for comment in early May, but I suspect it may be delayed.

- For information on this topic from past meetings, click here.

China – GB 28050-2025 National Food Safety Standard General Rules for Nutrition Labeling of Prepackaged Foods

- On March 27, 2025, the National Health Commission and the State Administration for Market Regulation jointly released 50 national food safety standards and 9 amendment sheets.
- Starting with GB 28050-2025, the last version is from 2011.


gb-28050-2025-食品安全国家标准-预包装


gb-28050-2025-食品安全国家标准-预包装

- EPA and DHA have been added to the optional labeling list.
- O-3 content claims have been added.
    - Source of n-3 polyunsaturated fatty acids (or ω-3 polyunsaturated fatty acids) OR Contains n-3 polyunsaturated fatty acids (or ω-3 polyunsaturated fatty acids)
        - The combined total of EPA and DHA ≥ 40 mg per 100 g (for solids) or 100 mL (for liquids)
    - High in or rich in n-3 polyunsaturated fatty acids (or ω-3 polyunsaturated fatty acids)
        - The combined total of EPA and DHA ≥ 80 mg per 100 g (for solids) or 100 mL (for liquids)
- Hywel: Is that a high in Omega-3 that requires both EPA and DHA to be present or can you say high in DHA, if that's all that's included in the product?
- Harry: I don't know, but I will go back and review to see if that question can be answered.
    - It does not appear that both EPA and DHA must be present, but it's not clear if you can state "High in DHA" if that's all you're including on the label.

- Michelle: This one and the third one down have been in discussion since 2017/2018 and there have been multiple drafts. For other nutrients, it's been very helpful because they've added nutrient effects or function claims. This is a major overhaul, so all labels will have to be updated as a result of this standard and GB 7718-2025. One is issued by SAMR and the other is issued by the National Health Commission (NHC). Together they've been working on this since about 2018. 16 March 2027 is the implementation date.

China - GB 25596-2025 National Food Safety Standard General Rules of Infant Formula Foods for Special Medical Purposes


gb-25596-2025-食品安全国家标准-特殊医


gb-25596-2025-食品安全国家标准-特殊医

- Scope has been increased from 6 months to 12 months.
- Revision to technical requirements for optional nutrients, including DHA.
  - Value per 100 kJ
    - Minimum
      - Prior: "not specified"
      - Updated: 3.6
    - Maximum
      - Prior: 0.5
      - Updated: 9.6
  - Value per 100 kcal
    - Minimum
      - Prior: "not specified"
      - Updated: 15
    - Maximum
      - Prior: 0.5
      - Updated: 40

China - GB 7718-2025 National Food Safety Standard General Standard for the Labeling of Prepackaged Food


gb-7718-2025食品安全国家标准-预包装食


gb-7718-2025食品安全国家标准-预包装食

- A key amendment in this new version is that allergen labeling became a mandatory labeling item, but refined fish oil and DHA from fish oil have been explicitly exempted.

US - FDA's Laboratory Developed Tests Final Rule Invalidated

- See 1 April 2025 FDA Law Blog.
- On March 31, 2025, a Federal Court overturned FDA's Laboratory Developed Tests (LDT) Final Rule. That Rule sought to codify FDA's view that LDTs are medical devices subject to FDA

regulation under the Food, Drug, and Cosmetic Act (FDCA) and then phase out, over a four-year period, FDA's purported policy of "enforcement discretion" for such tests.

US – National Organic Standards Board (NOSB)

8 April 2025 Update

- Harry: On the agenda for the spring meeting is a proposal from the Handling Subcommittee to correct the fish oil listing at 7 CFR 205.606 by deleting reference to CAS numbers 10417–94–4 and 25167–62–8. Those CAS numbers are for EPA and DHA, not fish oil, so they are technically incorrect. There's no CAS number for fish oil, so the listing won't include a CAS number. GOED will submit written comments supporting the proposal to remove the CAS numbers, but GOED will not deliver oral comments or tune into the meeting. When the meeting transcript is posted, Harry will confirm that the proposal was accepted.

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

NOT ON AGENDA AND NOT DISCUSSED

Mineral Oil

8 April 2025 Update

- Harry: The technical committee discussed mineral oils during their 13 March meeting. Here is a link to the meeting minutes.
- The next meeting of the EC's Expert Group on Industrial Contaminants and the Environment will take place on 6-7 May 2025.

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