GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3S

Regulatory Affairs Committee Meeting Minutes

Date: 28 January 2025
Last Meeting: 3 December 2024
Next Meetings: 25 February 2025

PRESENT
GOED Staff:
Gabriela Cortez
Chris Gearheart
Vicky Lin
Harry Rice
Ellen Schutt
Committee Members:
Helen Albans (Croda)
Jose Avalos (dsm-firmenich)
Shabnam Behnam (NOW)
Mia Eirin Brastad (Zooca)
Paul Browner (dsm-firmenich; chair)
Hywel Griffiths (Fermentalg)
Kelly Han (Supplement Certified Ireland)
Ingrid Jakobsen (Orkla)
Oliver Kromer (Imperial OEL Import)
Christine Krumbholz (KD Pharma)
Nicole Labate (Nestle)
Mikayla Ladimir (Pharmavite)
Abdou Lemseffer (Herbalife)
Jessica Mejía (Copeinca)
Jai Mishra (BASF)
Jon O'Farrell (Vivo Brands)
Stephane Pasteau (Cargill)
Deyanira Roman (Aker Biomarine)
Jorge Sepúlveda (Innocon)
Tina Lien Vestland (Golden Omega)
Erwin Weerts (Corbion)
Allison Wilkin (Nature's Way Canada)
Mo Youssefi (Nordic Naturals)

Global Omega-3 Navigator: Regulatory and Technical (formerly the regulatory map) – Demonstration

- See 3 February 2025 GOED Current
- Harry: The topics will be expanded over time. There are currently three. We believe the next topic is going to be food additives. We would like your feedback on what you would find useful. When you use the database, let us know if you find incorrect information or if you have information that we haven't included.

- Oliver: Will it be possible to track how much the tool is being used? Since it's an ongoing investment, it would be good to know how much it's being used and which parts are getting the most use.
- Ellen: We'll have to look into that.
- Paul: It's everyone's responsibility to provide feedback – changes, additions, etc…
- Paul: Why is the EU in green?
- Gaby: Since the EU has their own regulations and it's for many countries, it's green. There's a legend on top. If the regulation is country specific, then it will be blue. If a regulation applies to an organization (e.g. MERCOSUR) and a country (e.g. Brazil), then that will be yellow.
- Hywel: I was wondering if you could add a field for when the information was last updated in the database?
- Harry: This is a good idea and we just need to discuss the logistics internally.

Global Omega-3 Navigator: Regulatory and Technical (formerly the regulatory map) – Which Food Additives Should be Included?

- Harry: Below is a table of food additives that was created based on the Codex General Standard for Food Additives (GSFA) and then expanded based on feedback from the technical committee. For the food additives with a question mark next to them, if you are using them, please let us know and we'll include them in the GO-3N. For the food additives for which we don't receive confirmation of use, we won't include them in the GO-3N. If there are any food additives missing, please let us know about those as well. We will start with food additives used in the actual oil. Later, we will consider adding food additives that are used in powder formulations. If you want to include those now, please differentiate between the two uses. Please provide feedback by 14 February.
- Paul: Let's carry this agenda item over to the next meeting.

Food Additive	
Ascorbic Acid, L-	?
Ascorbyl Esters as Ascorbyl Palmitate	
Ascorbyl Esters as Ascorbyl Stearate	?
Astaxanthin	
Butylate Hydroxyanisole	
Butylate Hydroxytoluene	
Diglycerides	
Carotenes, Beta-	?
Carotenes, Beta-, Vegetable	?
Citric Acid	
Diacetyl tartaric and Fatty Acid Esters of Glycerol	?
Diglycerides	
Green Tea Extract	
Guaiac Resin	?
Isopropyl Citrates	?
Lecithin	?
Medium Chain Triglycerides	
Monoglycerides	

Mono- and Diglycerides of Fatty Acids	
Palm Oil	
Propyl Gallate	
Propylene Glycol Esters of Fatty Acids	
Rosemary Extracts	
Silicon Dioxide	
Sodium Ascorbate	
Starch Sodium Octenyl Succinate	
Stearyl Citrate	?
TBH	
Thiodipropionates	?
Tocopherols	
d-alpha-Tocopherol	
Tocopherol concentrate, mixed	
dl-alpha-Tocopherol	
Tocotrienols	?
Tricalcium Phosphate	
Trisodium Citrate	
Vitamin A as retinyl palmitate	
Vitamin D3 as colecalciferol	

EU – EC Working Group on Novel Foods

- Harry: The 23 January 2025 agenda of the Working Group on Novel Foods includes the following agenda item – "Request for a scientific opinion on the safety of supplemental DHA." GOED has been informed (unofficially) that this mandate stems from discussions in the context of a request for extension of *Schizochytrium* sp. (FCC-3204) oil. This is currently authorised for use in food supplements and infant/follow on formula and an extension for use in protein products. EFSA considered that this would not lead to significantly higher exposure of DHA. Nevertheless, the Commission has asked EFSA to establish a tolerable upper intake level for DHA and EPA. No publicly available documentation is available yet.
- Hywel: A while back, we requested that Schizochytrium oils could be added to protein products as part of the novel food catalogue because they aren't currently permitted for such use. The Commission then decided to attach that to the FCC-3204 oil, which is Fermentalg's oil and we went through the EFSA process and got an opinion back saying no problem. It's not going to lead to significantly higher exposure of DHA in the general population than would otherwise occur. As part of the submission, you have to provide an exposure estimation that is generated by the European Union tool which takes into account intake from every single population of every single country of the EU. It's a bell curve and at the far end of the curve you find people who may take a couple of grams per day. The issue is that EFSA hasn't assessed safety of omega-3s since 2012 at which point they concluded that there was plenty of evidence that EPA and DHA together were safe, but that there was no data demonstrating the safety of DHA alone above one gram/day. This worries the Commission, because EFSA has provided an opinion that even at the end of the bell curve with two grams/day it's safe; whereas, there's an opinion that states up to one gram/day is safe and past that the safety is unknown. We believe there will be a public consultation (timing unknown) on this

subject. When that happens, we can provide more recent publications where DHA alone has been used. If anyone else has information, I'm sure that it will be welcomed as well.

- Oliver: The worry could be AFib.
- Harry: I would be surprised if AFib isn't addressed given the warning that was put out by the European Medicines Agency (EMA) regarding pharmaceutical omega-3s. Since that time, GOED has been concerned that there would be an evaluation conducted on what would be an appropriate upper limit considering the risk of AFib. The evaluation was bound to happen sooner or later. If anyone hears about the outcome from the meeting, please let us know.
- Oliver: I do see a potentially harmful outcome in larger parts of the market where we've seen that higher dosage recommendations or higher dosages are being used. So I know that at least in Germany there are a number of companies that are targeting companies that are targeting either two grams of EPA+DHA per day or two gram of total omega-3s. I wonder if there is much more that we can do than just wait and see what EFSA decides.
- Harry: I think this is a real threat and GOED is very concerned about this. At the moment, GOED has a "position statement" on EPA/DHA Omega-3s and Atrial Fibrillation. We're going to have to figure out how to manage the message.
- Ellen: People probably remember that we commissioned another paper with the Fatty Acid Research Institute (FARI) to look at the other studies (~80) that exist on omega-3s and cardiovascular outcomes to see if AFib was tracked. Right now, there are nine studies reporting an increased risk of AFib with EPA/DHA ingestion. The challenge is that FARI is not finding a lot of additional data.
- Paul: Speaking with people in my company, the data that does show a risk seems to be noisy.
- Ellen: The media message will undoubtedly be different than the science. I think we wrote a good letter to the EMA last year saying that they were jumping the gun. See 10 November 2023 News Alert.
- Oliver: The last time EFSA did an evaluation for tolerable upper intake limits, they calculated the worst-case scenario which didn't align with reality. There are certain ways EFSA makes these calculations, and I think it's important to attack their methods.
- Harry: The person that we worked with for our report in 2012 was Aine Hearty and I think she's very good, but she's a challenge to work with.
- Oliver: I don't think you will change the way EFSA approaches the issue, but if you have good points to make, Member States are unlikely to just ignore those points.
- Hywel: I can offer my services having been through the exposure estimations very recently. I'm happy to run you through what we did.
- Harry: I'll reach out to you.

China - China to Amend GACC Decree 248 on Registration of Overseas Manufacturers of Imported Foods

- Harry: On January 3, 2025, the General Administration of Customs of China (GACC) released a revised draft of the Regulation on the Registration and Administration of Overseas Manufacturers of Imported Food. Stakeholders can submit their comments via email to cifer@customs.gov.cn by February 19. I can submit comments, but they will require significant input from committee members. Please let me know by February 14 if you would like me to submit comments and what comments you have.

- There are six key revisions: 1) Refinement of "System Recognition" Requirements, 2) Introduction of New Registration Methods, 3) New Catalog for Recommended Registration, 4) Adjustments to Re-registration Requirements, 5) Removal of Time Limits for Renewal Applications, and 6) Exemptions from Registration
- Notice of the General Administration of Customs on Soliciting Public Opinions on the Regulations of the People's Republic of China on the Registration and Administration of Overseas Manufacturers of Imported Food (Draft for Comments)
  - Appendix #1: "Regulations of the People's Republic of China on the Registration and Administration of Overseas Manufacturers of Imported Food (Draft for Comments)"


Appendix1_Chinese.docx


Appendix1_English.docx

  - Appendix #2: Revision of the Regulations of the People's Republic of China on the Registration and Administration of Overseas Manufacturers of Imported Food (Order No. 248 of the General Administration of Customs)


Appendix2_Chinese.docx


Appendix2_English.docx

  - Appendix #3: List of foods that require official recommendation registration letters (Draft for comments)
    - Includes aquatic products


Appendix3_Chinese.docx


Appendix3_English.docx

- To read the minutes from past meetings on facility registration in China, click here.

EU – DG SANTE (not discussed during the meeting)

28 January 2025 Update

- Harry: During the December meeting, we discussed the Final Report of an Audit of Peru Carried Out from 4 to 15 March 2024 in Order to Follow up the Implementation of the Actions Taken by the Peruvian Authorities to Address Certain Recommendations of Audit Report DG (SANTE)/2018-6390. What I didn't mention was the competent authority's response to the report recommendations. Note the response (i.e. Measure proposed by the competent authority) to recommendation #6 - *Ensure that only raw materials (unrefined fish oil) fit for human consumption are used in the production of fish oil for human consumption for export to the EU, as required by Section VIII, Chapter IV, point B of Annex III of Regulation (EC) No. 853/2004.*
  - Issue a communication to operators of oil processing plants for human consumption that export to the European Union, regarding compliance with the EU legal basis (VIII, Chapter IV, point B, of Annex III of Regulation (EC) No 853/2004 and that such compliance is detailed in their safety management systems (HACCP, GMP, etc.)
  - To issue a communication to the operators of crude fish oil processing
  - plants to declare the purpose of the product in all traceability documents, in health certification procedures for export purposes.

  - Update MEMORANDUM No. 288-2020-SANIPES/DHCPA on the Guidelines for the evaluation of crude and refined fish oil destined for the European Union, in order to consider the indication of the purpose of the products human consumption or non-human consumption, updating of current health regulations.
  - Update the format of "Record of evaluation for the attention of the request of the Services provided in Exclusivity", which will include the verification of the traceability of the fish oil, according to the declared purpose, in compliance with the EU health regulations.
  - Training for Health Controllers regarding compliance with Section VIII, Chapter IV, point B, of Annex III of Regulation (EC) No. 853/2004 and aspects related to the documentary traceability of certification dossiers for oil for direct and indirect human consumption.
  - To carry out sanitary control (traceability) of oil processing plants for direct human consumption that export to the EU.
- With respect to the issue of the alleged export of crude feed oil from Peru to other countries and then refining or concentrating it and shipping it to the EU as food grade oil (when it was only supposed to be used as feed grade oil), I mentioned during the last meeting that I had heard back from the United States. Since the last meeting, I contacted CFIA and they have replied with some follow-up question, which I have answered and now I'm waiting to hear back from them. Ellen asked IFFO about China and was informed that crude fish oil, upon receipt in China, is classified according to what the exporting country declared.
  - If that's the case for crude oil, then the same would be true for refined fish oil or concentrated omega-3 oil from fish. Given that the United States doesn't require knowing the grade (feed versus food) of oil being imported, if a company requests an export certificate from NOAA Seafood Inspection Program (SIP) for fish oil for human consumption and NOAA SIP has audited the company's facility for processing human grade oil then there's no reason to believe that the oil couldn't be exported to China as human grade oil.

- This topic has been discussed over many years. For information on this topic from past meetings, click here.

Codex – Standard for Microbial Omega-3 Oils (not discussed during the meeting)
28 January 2025 Update

- Harry: As I mentioned during the last meeting, the Codex Alimentarius Commission approved the proposal for New Work on a Standard for Microbial Omega-3 Oils. Before the holidays, Gerard and I provided comments back to the chair (United States) regarding the comments received from several Codex Member Countries in response to the first draft proposed standard. Then, earlier this month, we had a call with the United States for further discussion. The second draft proposed standard should be posted any day now, but there could be an issue if the United States withdrawals from the World Health Organization.

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

South Korea - Notice of Legislation on Partial Amendment to the Enforcement Decree of the Act on Labeling and Advertising of Food, etc. (Ministry of Food and Drug Safety Notice No. 2024-366) issued on 8 August 2024

- Includes fish oil, but is it relevant to only foods with fish oil and not fish oil supplements?

US – Dietary Guidelines Advisory Committee Report (not discussed during the meeting)
- See 16 December 2024 GOED Current

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

US – Allergen Labeling (not discussed during the meeting)
- See first story under "Regulatory & Certifications" in 13 January 2025 GOED Current.

US - Cardiovascular Claims (not discussed during the meeting)
28 January 2025 Update
- Harry will provide an update during the February meeting.

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

Dietary Reference Intakes (DRI) (not discussed during the meeting)
- Harry: GOED provided comments on all three fat-related protocols from AHRQ. Click here to access them. Once the draft reports are posted (timeframe unknown), the public will have thirty days to comment on them.

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

Thailand (not discussed during the meeting)
28 January 2025 Update
- Harry: As was mentioned in the minutes from the last meeting, in the 21 October 2024 GOED Current, under "Regulatory & Certifications," we asked if any members had reached out to the Thailand Food and Drug Administration (FDA) about registering their Schizochytrium oils with specifications deviating from the published specifications. We didn't receive any feedback. Should we remove this item from the agenda?

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

EU – Mineral Oil (not discussed during the meeting)
28 January 2025 Update
- See 18 December 2024 News Alert

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

GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3S

NOT ON AGENDA AND NOT DISCUSSED

Australia – Exports

- See WTO Notification dated 7 January 2025 entitled *Updates to sanitary certificates for exports from Australia of processed foods and beverages, edible animal fats and oils, vitamins and supplements, animal feed and feed additives, shells, fertilisers, and human and animal remains*.
    - New export certificates (Declaration and Certificate to condition) to be issued for:
        - Australian exports of processed foods and beverages, edible animal fats and oils, vitamins and supplements, animal feed and feed additives, shells, fertilisers and human and animal remains
    - This will commence from 10 February 2025, with a staged rollout until 5 May 2025.