GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3S

Regulatory Affairs Committee Meeting Minutes

Date: 25 February 2025
Last Meeting: 28 January 2025
Next Meetings: 8 April 2025

PRESENT
GOED Staff:
Aldo Bernasconi
Gabriela Cortez
Chris Gearheart
Harry Rice
Ellen Schutt
Committee Members:
Helen Albans (Croda)
Maria Albornoz (Pesquera Diamante)
Jose Avalos (dsm-firmenich)
Shabnam Behnam (NOW)
Jeffrey Blume (NOW)
Paul Browner (dsm-firmenich; chair)
Irena Brustad (Vitux/Concordix)
Hywel Griffiths (Fermentalg)
Kirsten Humphreys (Bare Biology)
Ingrid Jakobsen (Orkla)
Oliver Kromer (Imperial OEL Import)
Christine Krumbholz (KD Pharma)
Mikayla Ladimir (Pharmavite)
Pilar Lara (Innovaoleo S.L.U.)
Abdou Lemseffer (Herbalife)
Jon O'Farrell (Vivo Brands)
Stephane Pasteau (Cargill)
Deyanira Roman (Aker Biomarine)
Natalia Sánchez (Innovaoleo S.L.U.)
Michelle Stout (Amway)
Michael Strube (Orkla)
Allison Wilkin (Nature's Way Canada)
June Yao (Nuseed)
Mo Youssefi (Nordic Naturals)

Housekeeping
Harry: With respect to AI, we've decided within GOED that we're not going to allow our committee meetings to be externally recorded. In case you should launch an AI device to record the meeting, I'll bump it off.

GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3S

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

25 February 2025 Update

- Harry: The GO-3N was launched 3 February 2025 and can be accessed via the Member Portal, specifically under "Regulatory Information" or here is a direct link. You must be logged into the website in order to access the GO-3N, which means you will need to register for website access if you haven't done so in the past.
- See 3 February 2025 GOED Current
- Paul: Internally, there has been some very positive feedback. People like it.
- Harry: We are exploring how to best implement the "last revision date."

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

25 February 2025 Update

- Harry: I sent out the revised list with the agenda. We had a very good recommendation to include the source of the additive when it is variable. An example is for tocopherols which can originate from soy or sunflower. Obviously, this is an allergen issue and the source will be included. I'm going to turn the list over to Gerard to run past the technical committee one last time. Here is the most up-to-date list for review.

FoodAdditivesList_Revised7March2025.doc

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

EU – EC Working Group on Novel Foods

25 February 2025 Update

- During the last meeting, we discussed briefly that the European Commission (EC) has requested the European Food Safety Authority (EFSA) to reassess the safe level of intake of omega-3s. It turns out that it is specific to DHA.
- See the second story in 10 March 2025 GOED Current.
- Harry: While this is not an open consultation, we'll convene internally and discuss if/what we should provide to EFSA. Given that the request is specific to DHA, I don't know that the AFib issue will arise. We'll discuss this further during the next regulatory Affairs Committee call.

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

GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3S

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

25 February 2025 Update

- 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
- Harry: We didn't get a chance to discuss this topic during the last meeting, so Gaby is going to provide some information now.
- Gaby: On August 8, 2024, the draft of Enforcement Rule of Food Labeling Act was issued for public feedback and on December 30, 2024, the Ministry of Food and Drug Safety promulgated the revised enforcement rule which includes mandatory nutrition labeling that has been expanded to cover processed animal foods. Fish oils are included in the new list of foods subject to the mandatory nutrition labeling. Foods that are subject to nutrition labelling are listed in Appendix 4 and referred to in Article 6. Among other foods, there's edible oils, special nutritional foods, foods for special medical purposes, health functional food products and marine processed foods. Those are the ones I might consider to be relevant, but I would like to ask the committee if they think algal oils would be included in one of these categories?
- Harry: I can't remember if algal oils are referred to as algal oils in South Korea. I recall something about an indirect reference to algal oils. Paul, I think you and I had this discussion at some point. I think there was reference to seaweed.
- Jose: The interpretation has always been that the Korean Food Code refers to the agal oil as seaweed and that's where DHA is mentioned. There's no direct mention of algal oils.
- Ellen: So, the algal oils on the market in South Korea have nothing to do with this?
- Jose: Correct.
- Gaby: I would like to add that there's some foods that are excluded from nutrition labeling and those include foods, lifestyle products and health functional foods that are not provided to the final consumer in and of themselves, such as those used as raw materials for food, livestock products and health functional foods. I would like to also add that there's a section for labeling for consumer safety that includes an appendix that has an indication of allergens and within the allergens there's mackerel and squid listed, and the labeling target is foods, etc that use ingredients obtained by extraction, etc from foods that are part of this allergens list or used as raw materials. Note that "raw materials must be labeled regardless of the amount of allergens contained in the product."
- Harry: For clarification, is the amendment inclusive of all fish oils, but it's only fish oils from mackerel and squid that must be labeled as allergens?
- Gaby: Yes and regardless of the amount. All other fish are not included for the allergen warning. It reads, "however, if the product name of a food manufacturer or process with a single raw material is the same as the raw material name subject to allergen labeling then the allergen labelling may be omitted.
- Paul: So, if you name something as mackerel oil, then you don't have to list it as an allergen, because it's in the name of the primary display label.
- Gaby: Yes, and squid as well.

- Harry: That aligns with other countries, as well, but it's odd that it's only mackerel and squid that they call out.
- Paul: I don't know what the rationale is behind that and I don't think I've ever seen a single species mackerel oil. It's usually a blend or a mix. That's in contrast to tuna or salmon oil.
- Harry: So, if you end up with a mixed oil and part of the mix is mackerel oil, do you have to label it as an allergen? I suspect the answer is yes, but I'm not certain.
- Paul: It sounds like you would have to. If you have a mixed oil like a mackerel, sardine, and anchovy oil and you listed omega-3 fish oil on the primary display label, in some countries, if you put it in the ingredient list, you don't necessarily have to call it out as an allergen, but it's a bit unclear whether if it's in the ingredient list if you have to have the allergen warning statement below it or not.

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

Codex – Standard for Microbial Omega-3 Oils

25 February 2025 Update

- Harry: The Electronic Working Group (EWG), chaired by the United States and co-chaired by China, posted (19 February 2025) the second consultation on the development of a Standard for Microbial Omega-3 Oils. We are asking stakeholders for feedback by 14 March 2025 so we have sufficient time to compile our comments and get them back to the EWG. You'll note that there are many changes compared to the first version. This is a result of extensive comments from Codex Member Countries. This draft Standard remains very much in flux and requires your input and feedback, particularly where there is an absence of information. Oils without sufficient data (e.g. fatty acid information) are likely to be removed after this round of comments. Codex does not include named oils in its standards that are not commercialized.
- Hywel: Is there a path forward for new oils to be integrated into the standard at a later date?
- Harry: Yes and that's why it's written the way it is now as a microbial omega-3 oil standard. There was some discussion as to whether or not the standard should include oils other than omega-3s, because there are omega-6 oils that are of microbial origin. Provided the standard is eventually adopted, we can put in a proposal to amend the standard. For example, calanus oil was recently added the Standard for Fish Oils.
- Oliver: Regarding the commercialized quantities, what levels would be required in order to justify addition to the standard.
- Harry: There's no written standard. When the Standard for Fish Oils was being created, the threshold was supposed to be 10,000 MT in order to be a named fish oil, but there are named fish oils that aren't being traded at 10,000 MT/year. They sort of slid in at the last minute.
- Oliver: Like Nanochloropsis oils, where there are only a couple of companies developing and selling it, but it's very low volumes. From your perspective, would it be better to add them later?
- Harry: I think it could be better to add them later, but we included them in the draft standard because they are commercialized, and they have gone through a safety review in some countries. It's possible that the volume issue may be discussed during the next CCFO meeting and if it is then an arbitrary threshold could be set.
- Oliver: I think the problem is that there is no novel food approval yet in Europe, so probably the Europeans wouldn't be in favor of having those included.

- Harry: The EU is pushing back very hard in general, but they never called out Nanochloropsis. Their concern is any oil that they haven't evaluated and approved.
- Oliver: Might it be better to not make things more complicated and not include those oils at this time and then add them once there is a positive opinion from the EU?
- Hywel: I think Harry's point is that it's useful at this time to include them so that it becomes a microbial omega-3 oil standard and not just a Schizochytrium oil standard.
- Oliver: I agree with that approach.
- Michelle: The Codex process is so long that to go back and add stuff does take quite a bit of time. So, if they are being commercialized and you can get them in now, that's the way to go. The worst case is that the committee doesn't agree and they strike that one.
- Paul: 10,000 MT was the trade volume that was used for the Fish Oil Standard, and if I recall correctly that came up midway through that development, and I remember companies were asked to provide trade data. If this does become an issue, then I expect we would have to provide data.
- Harry: As far as the timing, Michelle's right that it would take a while and I would say that the shortest time it would take to add an oil to the standard would be four years because you have to put the proposal in to amend the standard. Then, it has to be discussed at CCFO, which only meets every two years. If they approve the work, then you come back two years later and discuss it again and if you're lucky, it will go through.

Working Document for Round 2.docx | Draft Standard for Round 2_tracked char | Draft Standard for Round 2_clean.docx

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

EU – DG SANTE

25 February 2025 Update

- Harry: I received a response from the CFIA, but they did not provide a direct answer to the query - "Does crude fish oil that enters Canada have to be accompanied by a certificate indicating whether or not it is classified as food (i.e. for human consumption consumption) or feed (i.e. for animal consumption) grade? When Canada issues the EU model health certificate for a company to export its fish oil (or concentrates from fish oil) to the EU, do you have to attest to the quality (food versus feed) of the oil that was used to make the refined/concentrated oil?" Given the indirect way the CFIA replied, it seems that they don't require knowing if the imported oil will be going to the feed or food industry. They seem to only care that if it ends up being consumed by humans that it's safe.
- Harry: We've received an additional question along the same lines as the one regarding the United States and Canada. The question is as follows: "What is required to obtain an EU export health certificate from the Chinese Government?"
- Harry: Our understanding is that China requires knowing whether the imported oil is food or feed grade, but do they designate it as food or feed grade when it is exported? The overriding question is whether or not you can import feed grade oil into a country and export it to the EU as food grade oil? If you can, then I think there is a desire by some members to approach DG SANTE and have a discussion with them.
- Oliver: I don't understand why we keep having this discussion. I think it's clear that the EU regulations set certain standards on the origin of crude oil that is processed into refined oil that are

ending up in the EU. That is where the veterinary officers come into play from those countries where the oils are manufactured. Those veterinary officers may have their own understanding of the EU Hygiene Regulations and they may find that it is not necessary to check if the incoming crude oil complies with the EU's requirements. If the EU audits a facility that is not in compliance then they will block oil from it. What happened in Peru could happen in any country.

- Paul Browner: The EU has a specific template it uses for health certificates and it's up to the government of those countries wherever the products are made to make a decision based on the template and if all of the information on that health certificate can be satisfied by the local government, based on the manufacturing and processing of the oil that is coming out of a facility in a particular country, and they are willing to sign off and issue a health certificate, then they get a health certificate. Other regions may dig in a little bit more and of course we know that the Europeans will conduct audits in certain countries to validate what's happening and that's what happened in Peru. I don't know that GOED can do anything here. The EU has a template and we can't revise the template. Countries will assess based on the template and the information provided and then issue a health certificate if they feel that the requirements are met.
- Ellen: You just said that the EU has this template and there's nothing that GOED can do to change it. If this comes up as a formal request, we will come to the committee to talk about it.
- Harry: The EU export health certificates are agreed upon between EU and the exporting country, so, when the oil is exported from the United States to the EU, the certificate that's used has been agreed upon between the EU and the United States. This is one of the reasons why there was an issue with composite products for so many years. That is, there was no agreed upon certificate. Every country uses a different certificate that has been agreed upon. The EU has basically signed off on what they'll accept from a given country.
- Oliver: It comes down to basically the same thing and that is that there are different ways for the EU to be assured that their requirements are met by local regulations. In practice, the veterinary officer confirms with his signature that he has read and understood the EU Hygiene Regulations and that everything is fine. I don't think it's realistic to think that you can get the EU to change the Hygiene Regulations.
- Paul: I agree. If they open up the opportunity to negotiate health certificates, then maybe you can do it. Otherwise, I think it would be a waste of resources and time to try to tackle this as an industry association.
- Michelle: It sounds like we should remove this item for the next meeting.
- Harry: Consider it removed.

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

US - Cardiovascular Claims

25 February 2025 Update

- Harry: On 18 February, I updated the status of the six known class action lawsuits related to cardiovascular claims.

1) Hamzeh v. Pharmavite 4:24-cv-00472-HSG
    - Filed: 1/25/2024

- Court: California Northern District (Oakland)
- Status: 2/18/2025 – The last entry is 9/10/2024 and is nothing significant.

2) Anthony Fasce v. Nestle 7:24-cv-01009-PMH
   - Filed: 2/9/2024
   - Court: Southern District of New York (White Plains)
   - Status: 11/20/2024 – The last entry was on 10/29/2024 when the plaintiff filed memo to change allegations from national to be limited to New York.

3) Magpayo v. Walmart Inc 3:24-cv-01350-WHO
   - Filed: 3/6/2024
   - Court: California Northern District (San Francisco)
   - Status: 2/18/2025 - Hearing on motion to dismiss conducted on 2/12/2025. Motion taken under submission and written order to issue.

4) Clark et al v. Nordic Naturals 5:24-cv-04058-EKL (originally SVK)
   - Filed: 7/3/2024
   - Court: California Northern District (San Jose)
   - Status: 2/18/2025 – Hearing on motion to dismiss held on 2/5/2025. Motion taken under submission and written order to issue.

5) Yesenia Bowler v. Nestl Health Science U.S., LLC 2:24-cv-6521
   - Filed: 8/1/2024
   - Court: California Central District (Western Division - Los Angeles)
   - Status: 2/18/2025 – On 1/28/2025, the following judgement was declared - "Pursuant to the Courts order granting a motion to dismiss, it is ordered, adjudged, and decreed that judgment is entered in favor of Defendant Nestl Health Science U.S., LLC, doing business as Nature's Bounty, and against Plaintiff Yesenia Bowler. Plaintiff's claims are dismissed with prejudice. She shall take nothing from this action."

6) Costan v. Costco Wholesale Corporation v. Costco 3:24-cv-02156-JO-AHG
   - Filed: 11/18/2024
   - Court: California Southern District (San Diego)
   - Status: 2/18/2025 - On December 10, 2024, the Plaintiff in this matter voluntarily dismissed all claims against the Defendant and the case was closed.

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

Japan – Food with Function Claims

- On 17 January 2025, Japan's Consumer Affairs Agency (CAA) issued Proposal No. 235080079 detailing notification methods and required documents for Foods with Function Claims (FFC). We asked Takeshi Takeda at Global Nutrition Group (GNG) in Japan about this proposal because we thought it might be linked to an issue we reported on in the 4 August 2023 GOED Current. He provided some additional perspective.

  - Takeshi Takeda: *The core of the system has not changed. Procedurally, what was previously regulated by guidelines (notifications) will now be regulated by law (Food Labeling Act) and government ordinance (Cabinet Office Ordinance). What was previously a "request" will now become an "obligation." This does not mean that the notification process will become more difficult, however, it will result in stronger regulations on quality control systems (e.g., GMP compliance) and annual reporting requirements. As a result of this change, more companies are withdrawing their notifications, with 25% of previous notifications already withdrawn. I believe the number of withdrawals will continue to increase. On the other hand, notifications for new ingredients and new health claims have increased.*
- Michelle: In case people don't know the background on this, it's related to the contamination of a non-omega-3 product (i.e. red yeast rice) last year. That's why there's a tightening of GMP and ingredient management. Our team has said that it's more of a paperwork exercise. So, if you have your ducks in a row, you should be fine. Everything that has been notified has to be set up in this new format which may be the reason there's a lot that's being pulled.
- Harry: Have the GMPs been revised?
- Michelle: There's a list of required documents that have been updated and things that have gone from recommended to required. Anything that was already notified and on the market must go back and redo all of their documentation.
- Michelle followed up after the call and provided the below information
  - Here is the Japan Foods with Function Claims (FFC) regulatory revisions and grace periods information. Points 2, 3 and 5 associated with health hazard information gathering, self-assessment, and new ingredient review period don't have grace periods.

Revision points	**Effective date**
1. Compliance with GMP standards in the manufacturing and quality control of tablets and capsule products is mandatory.	01-Sep-24
	2-year grace period
2. Obligation to collect information on health hazards by notifiers and to report suspected health hazards (limited to those diagnosed by a physician) to the CAA Director General and prefectural governors, etc.	01-Sep-24
3. Mandatory self-assessment of compliance by notifiers and reporting of results to the CAA Director (annually).	01-Apr-25
4. Labelling requirements revision	01-Sep-24
	2-year grace period
5. The deadline for submission of notification materials for new functionally involved ingredients is 120 business days in advance (usually 60 business days in advance).	01-Apr-25

GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3S

US – Dietary Guidelines Advisory Committee Report (not discussed during the meeting)
25 February 2025 Update

- Harry: See 10 February 2025 letter

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

NOT ON AGENDA BUT DISCUSSED

EU – Labelling Antioxidant Blends

- Natalia: In Europe, if you have a fish oil with a blend of three antioxidants, do you need to list each of the three antioxidants?
- Hywel: If you take the example of a mix of tocopherols, ascorbyl palmitate, and lecithin, then you would have to mention each of them. The only slight variation is that there are blends of ascorbyl palmitate that use lecithin to get ascorbyl palmitate into solution and in that case you can argue that the lecithin is not acting as an antioxidant in your oil and therefore you may not need to label it, but you can't just say blend of antioxidants. I don't think you need to necessarily say how much of each antioxidant is in the blend, but you would need to list the antioxidants in descending order by percentage of weight and the blend manufacturer should be able to tell you that.
- Harry: Here's a link to additional information on labelling food additives in the EU.

NOT ON AGENDA AND NOT DISCUSSED

- Canada updated the Krill Oil Monograph at the end of January. Here's the link.