GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3S

Regulatory Affairs Committee Meeting Minutes

Date: 28 November 2023
Last Meeting: 31 October 2023
Next Meeting: 30 January 2024

PRESENT
GOED Staff:
Aldo Bernasconi
Harry Rice
Kaitlin Roke
Ellen Schutt
Allison Wilkin
Committee Members:
Helen Albans (Croda)
Jose Avalos (dsm-firmenich)
Paul Browner (dsm-firmenich)(co-chair)
Irena Brustad (Vitux/Concordix)
Geeta Dinani (Algarithm)
Olenka Espinoza (Copeinca)
Ingvild Flatten (Aker)
Chi Hee Kim (Herbalife)
Christine Krumbholz (KD Pharma Group)
Nicole Labate (Nestle)
Kristin Latzo (Pharmavite)
Guido Medina (Pesquera Diamante)
Shirin Nia (Nature's Way Canada)
James Peach (Mara Renewables)(co-chair)
Deyanira Roman (Aker)
Michelle Stout (Amway)
Alexandra Rosemberg (Solutex)
Mo Youssefi (Nordic Naturals)

Canada – Changes to Fish Oil Monograph

- See first story in 13 November 2023 GOED Current
- Harry: I sent NNHPD an email with the following text:

  It appears that text may have been added to the fish oil monograph to exclude concentrated omega-3 oils from fish oil. If that was the purpose of the text, there is other added text that is contradictory.

  The first text in question reads as follows, "This monograph only covers naturally occurring amounts of fatty acids in fish oil and would not cover fish oils that are concentrated or spiked." This contradicts information found as a footnote to Table 1, which reads, "Includes fish oil in its natural and/or triglyceride/triacylglycerol form and/or esterified form."

  The reason the information is contradictory is that esterified forms of omega-3s from fish oil are considered concentrated.

If possible, it would be great if you can clarify the purpose of the text additions so that I can tailor GOED's comments and not have to address different scenarios (concentrates included versus excluded).

- Harry: The following is the response I received from NNHPD:
  Thank you for your question. We agree that this information is unclear. As we would like to provide more flexibility and as many licensed fish oils are in fact concentrated, we will remove the term "concentrated" from the introductory statement and revise it to : "This monograph only covers naturally occurring amounts of fatty acids in fish oil and would not cover fish oils that are spiked".
- Harry: While NNHPD's proposed modification isn't perfect, it does tell us that they weren't trying to exclude concentrates.
- Paul: I suggest modifying NNHPD's statement as follows - "This monograph ~~only~~ covers naturally occurring amounts of fatty acids in triglyceride forms and concentrated ethyl ester forms in fish oil and would not cover fish oils that are spiked."
- Harry: Should we remove "spiked?"
- Michelle: The genesis of all of the monographs being reviewed and updated is to align with the new labeling requirements. I'm wondering if that has something to do with how it would be named. If you're naming something from natural fish oil, if it's been spiked, that would be misleading. Maybe you could put in a question with the comments to see if they can clarify the rationale for "spiked." Also, refer them to the Codex Standard for Fish Oils regarding named and unnamed fish oils.
- Paul: When does the consultation close?
- Harry: Friday, December 1.
- Paul: My concern is that we're dealing with someone who doesn't really have a grasp on the topic. I suggest we submit very poignant comments in advance of the deadline.
- Harry: We should be able to get comments in by the end of tomorrow because they aren't going to be extensive. I have my doubts that they will reply in a timely manner given how long it took them to reply to my first email. I think we need to be very specific so there is not a lot of room for misinterpretation.
- James: Make sure to include re-esterified triglycerides.
- Harry: So the modification would be as follows: "This monograph ~~only~~ covers naturally occurring amounts of fatty acids in triglyceride forms and concentrated ethyl ester and triglyceride forms in fish oil and would not cover fish oils that are spiked."
- Michelle: Regarding proposed removal of "Includes pregnant and breastfeeding woman," perhaps this is because the EFSA 2012 reference does not call a different max level for this subpopulation and the 5 grams applies to all. In the other monographs, there is only a separate indication for this subgroup if the levels are different. I suggest confirming in comments by making a statement like "We're supportive of the max level being the same for the general population and pregnant and lactating women, but want to confirm that this is why you proposed deleting footnote 3 in Table 2 which reads, "Includes pregnant and breastfeeding women."
- Harry: Several hours after our call, a committee member informed me that the NNHPD consultations for the monographs, including the one for fish oil, were extended until January 29, 2024.

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Amazon – Delisting Products with Heart Health Claims (not on original agenda)

- Harry: A GOED member has informed us that Amazon delisted (without warning) some of his products because of generic 'heart health' claims or 'supports cardiovascular health' claims. In addition, other products are getting delisted for the same reason, but aren't associated with any heart health claims. The member heard from his Amazon Account Manager (an Amazon employee whose job is to assist us in such matters) that his company is not the only one. It's apparently platform wide. The member appealed the decision to Amazon and Amazon denied it. Below is the first part of the delisting notice.
    - *This product has been identified as claiming to be a treatment, cure, or remedy for cardiovascular or related heart diseases or conditions such as blood clots, cardiac arrest. Products including dietary supplements, essential oils, homeopathic remedies and topicals marketed as products for cardiovascular treatments, remedies, cures, or similar disease-related products are prohibited unless they have been approved by the FDA. To be considered for reinstatement, please remove the prohibited disease claim from the detail page and appeal the restriction. Please note that if the disease claim is on the product labeling, there may not be a path to reinstatement. For more information please see https://sellercentral.amazon.com/gp/help/external/help.html?itemID=200164490&language=en-US&ref=efph_200164490_relt_202115120 and https://www.fda.gov/news-events/press-announcements/fda-warns-seven-companies-selling-dietary-supplements-claims-treat-cardiovascular-disease.*
- James: I haven't heard about this from any of our customers. In Canada, there's a much broader list of claims that can be made when you consider NHPs versus supplements (US).
- Harry: I suspect whoever is doing the delisting doesn't have a lot of familiarity with the regulations (i.e. structure/function claims). It's interesting that Amazon is cracking down on generic structure/function claims, but not addressing things like testimonials.
- James: Let Harry know if you hear about anything.

US – Brain Health Claims

- Harry: GOED is aware of one class action complaint and two demand letters regarding brain health claims.
- Harry: The claims from the original class action complaint are: 1) mental focus, 2) cognitive support, and 3) neurological health. The complaint was modified in May and the claims being questioned have been extended/modified to include: 1) "optimize immune function"; 2) "supports brain health"; and 3) "clinically shown to support a healthy heart." It's troubling that "supports brain health" was called out given that the claim is so basic and the wording is within the realm of what is permitted by regulation.
- Harry: For those not familiar with demand letters, they are letters, usually written by an attorney on a client's behalf, outlining the dispute between the two opposing parties and demanding that the recipient of the letter take or cease a certain action. The purpose of a demand letter is to begin the

negotiation process that will hopefully result in dispute resolution to avoid filing a claim in court if it is possible to resolve the issue without litigation.

- Harry: Of the two companies that we know received demand letters, the one company settled and the other company is in the process of settling. The reason for settling is usually to avoid high costs associated with fighting a lawsuit.
- Harry: If anybody hears anything relevant, please let us know so that we can share (anonymously) more broadly.
- James: I feel like this isn't the first time there were issues with brain health claims in the United States. I wonder if you win a settlement against one company, do you find the next company making the same claim and file the same lawsuit?
- Paul: That seems to be the strategy.
- Harry: Regarding omega-3s and brain health claims, I suspect there are many more demand letters and perhaps class action lawsuits, but we just haven't heard about them, at least yet.
- Harry: There was an FTC case.
    - After the call, I found a couple of FTC cases related to omega-3s and brain health. One finished in 2010 and the other finished in 2014.
- James: If you were to successfully refute one of these cases, it would be great if there were a list of the associated claims so that they couldn't be the subject of litigation again.
- Harry: In the US, and I suspect other countries, cases can be used as precedent to support arguments. The higher the court where the case was tried results in a stronger argument for precedent.

US – Federal Trade Commission Warning Letters Regarding Influencer Testimonials

- See first story under Highlights in 20 November 2023 GOED Current
- Harry: FTC has been clear for years that disclosure is mandatory.
- James: FTC fines can be costly.

Thailand – Algal Oils

28 November 2023 Update

- James: In 2022, we became aware that Thai FDA published a standard for algal oil which included a detailed fatty acid profile. GOED provided feedback on the standard/regulation. Specifically, the recommendation was to limit the fatty acid profile to only EPA and DHA. Subsequent to that, there was a new draft that was published that included a modified fatty acid profile, but still included more than EPA and DHA. Does anyone know the status? Is anybody in touch with Thai FDA?
- Jose: We haven't had any other communication with Thai FDA. As far as I know, they are still considering some of the comments we submitted.
- Harry: I know the last draft standard was in 2021, which is the one we commented on. I thought that was supposed to go into effect two years later, but I don't know if it did and I can't find anything. If that hasn't gone into effect, what standard would they be registering products against?
- Jose: Nothing changes until the law goes into effect. Every time the Thai FDA is approached, the response has been that they will consider our comments and recommendations, but nothing ever happens.
- Michelle: from a process perspective, there are a lot of drafts out there in Thailand and other areas that may linger for quite a while. The two year clock doesn't start until they are officially published. I can also inquire with our team to see if there's any movement on this draft.

- Harry: Are you still able to sell product in Thailand?
- Jose: Legacy products are still on the market, but for any new customers, we inform them of the situation and they then decide if they want to proceed with registration.
- Michelle: I don't know if we have an algal oil in Thailand.
- Jose: I will follow up with my colleagues in Thailand.
- Harry: Here is a link to registered products in Thailand that are returned when you search for "algal oil" and here is a link to registered products that are returned when you search for "schizochytrium."

- This topic was last discussed on 25 October 2022. To see minutes on this topic from past meetings, click here.

Australia/New Zealand - Call for comment to extend the use of rosemary extract as a food additive

28 November 2023 Original Discussion

- Call for comment to extend the use of rosemary extract as a food additive
- Harry: At first, I thought GOED should submit comments in support of the consultation, but upon further consideration, it isn't necessary since rosemary extract is already listed in the current standard as a permitted food additive for fish and algal oils at 50 ppm.
- Paul: Is 50 ppm the same level as the EU?
- Harry: I believe it is.
    - Commission Regulation (EU) No 1130/2011 of 11 November 2011 amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives by establishing a Union list of food additives approved for use in food additives, food enzymes, food flavourings and nutrients

E number of the added food additive	Name of the added food additive	Flavouring Categories to which the additive may be added	Maximum Level
E392	Extracts of rosemary	All flavourings	1000 mg/kg (expressed as the sum of carnosol and carnosic acid) in flavourings

- James: Is that ok?
- Paul: It depends upon whether you're using it as an extract of a natural flavor or as a food additive. As far as the level is concerned, I think the 50 ppm is ok. I wonder how it's broken down to carnosol and carnosic acid. I recall those causing some issues.
- Jose: The limit in the EU is 50 ppm for algal and fish oils. There are 4 types of extraction.
- Harry: In the EU, does it have to be declared as a flavor versus a food additive?
- Jose: If you are going to declare as a food additive, you must meet the purity requirements. You could declare as flavor, but there are specific requirements.

- Harry: The requirements for flavors versus food additives are not the same?
- Paul: They're not and you have to justify their use as a flavor. It's all very complicated. We don't need to dig into this on this call.
- Harry: I agree, but once the additional safety information is provided to JECFA and they've provided an ADI versus just a temporary ADI, this will go to CCFA for discussion for inclusion in GSFA. At that point, it's going to be very important to be involved in that discussion to ensure that rosemary extracts are included to be most advantageous for the industry.
- Michelle: It might be a good idea to talk to Cynthia Rousselot (IADSA) about this. She's very much an expert in CCFA and the JECFA reviews. She might be able to give you some insight into what we should do to prepare for the discussion and also to have IADSA advocate for the same position.
- Rosemary extracts as it relates to Codex has been discussed extensively over the years. Here's a link to past discussions.

Canada/US – DRIs Update

- James: I asked Harry if there was anything new to report.
- Harry: There's no news on when a DRI review for lipids (including EPA/DHA) will occur. Canada and the US have updated the Energy DRI. There's a Standing Committee for the Review of the Dietary Reference Intakes Framework and that committee addresses questions relevant to the DRI framework and structuring new DRI reviews as questions arise from various DRI consensus committees. The Standing Committee last met in August and discussed AMDRs (Acceptable Macronutrient Distribution Ranges). At this point, there is no formal commitment from either Canada or the US to fund the macronutrient reviews, yet there is work being done in anticipation of formal DRI reviews. For example, the Agency for Healthcare Research and Quality (AHRQ) is in the process of conducting a systematic review on "The Effect of Protein Intake on Health." The purpose of the review is "to provide an up-to-date and comprehensive key summary of evidence for dietary protein intake and risk of bone disease, kidney disease, and sarcopenia for a future U.S. and Canadian government protein DRI panel review of DRIs for an optimal protein intake." I have heard that the same type of systematic review will be undertaken for carbohydrates. While I haven't heard anything about lipids, it only stands to reason that one would be conducted. Previously, the NIH Office of Dietary Supplements commissioned the AHRQ to conduct a review of omega-3s in anticipation of a DRI review. That review was published in 2017 and was poorly done. After three years, the report was considered outdated.

- This topic has been discussed over the years, with the last discussion during the 31 January 2023 Meeting. To see the minutes on this topic from past meetings, click here.

CCFO – Algal Oil Standard

28 November 2023 Update

- James: My recollection is that we were looking for a country to champion this work. Is that correct?
- Harry: Yes
- Paul: In dsm-firmenich, we're active in all of the Codex committees and we have contact with many Codex Member Countries (CMC). We didn't hear back from any of them, but Canada. The head delegate for Canada seemed very interested. She was very active and supportive of the Standard for

Fish Oils. She hasn't committed, but has asked questions. I won't go as far as to say that she will chair the electronic working group, but the interaction was still positive.

- Harry: GOED's Proposal for New Work was uploaded to the Codex website on 21 November 2023. See agenda item 8.2 (Proposals for new work - Replies to CL 2021/96-FO). It appears to be the only Proposal that CCFO will be discussing at the upcoming meeting. What we're going to do now is generic outreach. David Pineda is going to draft a short memo to delegations and GOED will send it to the different Codex Member Countries (CMC), along with the Proposal for New Work and the updated trade data. We (Harry, Gerard and David) are going to schedule meetings with CMCs on the Sunday before the plenary starts.
- Paul: Is IADSA aware of the Proposal for New Work yet and do they support it?
- Harry: I haven't reached out to them yet, but plan to.
- Harry: If any committee members are selling an algal oil, it would be great if you would reach out to your CMC. If there are any questions about how to do that, let me know.

- This topic was first discussed during the 26 July 2022 meeting. For information on this topic from past meetings, click here.

Europe - COMMISSION DELEGATED REGULATION (EU) …/... of 15.9.2023 amending and correcting Delegated Regulation (EU) 2022/2292 with regard to requirements for the entry into the Union of honey, meat, highly refined products, gelatine capsules, fishery products and requirements for private attestation and amending Delegated Regulation (EU) 2021/630 as regards private attestation requirements for composite products exempted from official controls at border control posts

28 November 2023 Update

- I have not heard back from any members that this is having an impact on their business.
- I haven't heard back from Steven Wilson (US Seafood Inspection Program), so I need to follow up with him again.

- This topic was first discussed on 26 September 2023. For information on this topic from that meeting, click here.

EU – Mineral Oil

28 November 2023 Update (did not discuss during the meeting)

- See first story under "Highlights" from 4 December 2023 GOED Current.

- This topic was first discussed on 25 January 2022. For information on this topic from past meetings, click here.

China - Complete Nutritional Formula Food for Tumors

28 November 2023 Update (did not discuss during the meeting)

- HBR: I just want to bring closure to this agenda topic. As mentioned in the notes from the last meeting, the Draft Standard mentions omega-3s.

  - "3.4.3 The energy supply ratio of fat is 25%-50% and the energy supply ratio of n-3 fatty acids (calculated as EPA and DHA) should be 1%-6%, of which EPA content is not less than 50%."
- The deadline for feedback is 15 December 2023, but I don't recommend we submit anything since EPA/DHA are already mentioned.
- This topic will drop off the agenda unless a committee member requests for it to remain.

- This topic was first discussed during the 31 October 2023 meeting. To see the minutes from that meeting, click here.

NOT ON ORIGINAL AGENDA AND NOT DISCUSSED

US – Import Provisions of the Marine Mammal Protection Act (not discussed during meeting)

- On November 16, 2023, the Department of Commerce and NMFS issued a Federal Register notice extending the exemption period by two years, to December 31, 2025, for foreign nations to receive a Comparability Finding for their commercial fishing operations to export fish and fish products to the United States - a revision to the regulations implementing the import provisions of the Marine Mammal Protection Act.

- This topic was last discussed during the 26 July 2022 meeting. To see minutes from past meetings, click here.