GOED Technical Committee - Minutes

Date: January 30, 2025

PRESENT (please let us know if you were present, but not listed below)

Jenna Ritter (*chair* – Nature's Way of Canada) Manuel Reyes (Colpex) Luke McPherson (Mara Renewables) Simone Staiger (Eurofins) Guro Solberg (Pharma Marine) Tony Bimbo (International Fisheries) Linda Saga (Eqology) Rafa Gracia (Solutex) Tim Johanek (Carlson Laboratories) Jorge Sepúlveda (Innocon) Ingjerd Lystad (Pharma Marine) Mina Fakhary (Pharmavite) Katrina Bartley (Nutrasource) Anthony Bible (Wiley Companies) Marita Buarø (GC Rieber/Vivomega) Roberto Valenzuela (Innocon) Kelly Han (Supplement Certified) Erik Fuglseth (Orivo) Gerhard Kohn (Vesteraalens) Arnar Halldórsson (Lysi) Heike Meyer (Imperial Oel) Lina Cekaite (Aker Biomarine)

GOED Staff: Gerard Bannenberg (GOED) Gaby Cortez (GOED)

Guests: Daniel Bohlen (KD Pharma)

Absented:

Chris Gearheart (GOED) Inge Bruheim (Rimfrost) Frank Möllering (NutriSwiss) Thomas Ringheim-Bakka (Arctic Bioscience) Lilian Thiaux (Olvea)

Hyun-Ah Kim (Nutrasource/SGS) Lars Dalheim (Nofima) Geir Frode Olsen (Epax Norway/Pelagia) Davina Nagington (Croda) Henriette Meiser-Zessner (KD Pharma) Yutong Wang (Nutrasource/SGS) Nils Billecke (Cargill) Yanjun Zhang (Herbalife) Johannes Kraft (Evonik) Tina Vestland (Golden Omega) Vibeke Bløndal (BASF) Brad DaDalt (Jamieson Laboratories) Meagan Eggebeen (Amway) Helen Albans (Croda) Jennifer May (dsm-firmenich) Sonia Casanova (Copeinca) Guido Medina (Pesquera Diamante) Kenny Sharp (dsm-firmenich) Michelle Stout (Amway) Keith Person (Eurofins) Ágata Szygula (TASA) Osvaldo Barraza (Naturmega) Andrew Jenkins (Lipid Analytical Labs)

Harry Rice (GOED) Ellen Schutt (GOED)

Bas Arntz (Novosana) Roberto Fronzoni (KD Pharma) Eline Verbaanderd (Friesland Campina) Viorel Marculescu (MBP Solutions) Christine Krumbholz (KD Pharma) Christine Bousses (Fermentalg)

Invitees for this call:

Approval of Agenda and Minutes (Jenna Ritter - committee chair)

- Any comments on the minutes of the last meeting?
 - o No comments. The minutes of the last meeting were approved.
- The agenda and meeting documentation were sent out on December 17th, 2024. Any additions or changes?
 - o The agenda was approved.

New Technical Committee Members (Jenna Ritter)

• New members of the Technical Committee

- o Ozan Oğul (EasyVit) not present
- Guro Solberg (Pharma Marine) My name is Guro, and I have a background in industrial chemistry and biotechnology. I have been with Pharma Marine for almost 4 years now, and I recently started in the position of R&D Manager.
- o Margaret Liu (ATK Biotech) not present
- o Maria Svantesson (MBP Solutions) not present
- <u>Members who have left the committee:</u>
 - o Ilke Balci (EasyVit)
 - o Miranda Yang (ATK Biotech)
 - o Viorel Marculescu (MBP Solutions)
 - Jenna We also want to thank the three members who have left the committee. Thank you for your contributions.

Monograph/Pharmacopeia Updates (Gerard Bannenberg - GOED)

- Update of Guidance Documents Quantification of other omega-3 fatty acids
 - Gerard In the documentation for this committee call, together with the agenda, you have received the document that we discussed in the last committee meeting. It contains the text that explains how to calculate the content of individual omega-3 fatty acids that are not EPA and DHA, which we have proposed to add to the guidance documents. While the Guidance Documents (link) currently provide guidance on the quantification of EPA, DHA and Total Omega-3, We thought it could be helpful to also include information in the Guidance

Documents about how to determine the content of the other five omega-3 LCPUFA species, that together with EPA and DHA make up Total Omega-3. These "other" omega-3 fatty acids are C18:3 n-3, C18:4 n-3, C20:4 n-3, C21:5 n-3 and C22:5 n-3. You all have had a chance to look at this. We did not receive any comments, so we would like to propose that we approve it. If anybody does still have a comment, please speak up now.

Henriette Meiser-Zessner (KD Pharma) - I just wanted to say that it is a good proposal to add this. It makes it possible for everybody to really calculate these single fatty acids correctly. It is a good proposal, I agree.

Gerard – Thank you for that comment. If there are no objections from the committee, then I will proceed with including that text in the guidance documents, and you will get a copy of the updated guidance documents at some point.

No further comments or objections received from the Technical Committee

• Action item – Include the proposed text on the calculation of five other omega-3 fatty acids in the Guidance Documents (Gerard Bannenberg, GOED)

• USP-NF pre-posting; Temperature excursions

Gerard – Just a short note about something that was posted by the United States Pharmacopoeia (USP; Dec 24, 2024 - <u>link</u>), regarding the control of temperature during storage and transportation of drug products. While this text is not applicable to dietary supplements, it provides valuable information on how to calculate what is called the mean kinetic temperature (MKT) in countries in climatic Zone IVb. MKT is a parameter that can be used to understand the time history of a product's temperature exposure, which can help in better understanding the effects of temperature on product quality. Zone IVb countries are countries or markets that have an average temperature of 30°C and a high relative humidity of 75% on average. If such environmental conditions are of relevance to your omega-3 product, you may want to have a look at the chapter to see how this type of assessment is being carried out. Actually, it is a pre-posting of an update to method 1079.2, and the proposed text is already posted on the USP-NF website (free access - <u>link</u>).

Legislative Updates (Gerard Bannenberg)

- EU Bisphenol A ban in food contact materials
 - Gerard Just a few days ago, on January 20, 2025, a new European Commission (EC) regulation (EC Reg 3190/2024 of 24 December 2024 <u>link</u>) has entered into force that literally bans the use of bisphenol A (BPA) in food contact materials. This regulation is of

relevance because it affects GOED members with finished products on the market, at least in Europe. The regulation also extends to BPA salts and bisphenol derivatives and other bisphenols like bisphenol S. These are widely utilized as monomers in the production of epoxy resins and polycarbonate plastics. Some level of unreacted free bisphenols will always remain in the plastic, and which has the potential to leech into food that is in contact with the material.

The regulation has a transition period of 18 months. The bisphenol ban is based on the very high BPA toxicity, especially to the immune system. EFSA determined a tolerable daily intake in 2023 (<u>link</u>) of 0.2 ng/kg bw, which is extremely low. Since BPA is widespread in the environment and present in food at low levels, it may not actually be feasible to regulate such a low intake by setting a strict maximum limit of BPA in food, as all food would have to be banned. Hence, there are currently no regulations for BPA in food yet. It is unclear if, and not impossible that, at some point, the EC is also going to regulate bisphenols in food, now that its use is banned in food contact materials.

This new regulation has some implications. For example, you may want to check the BPA level in the plastic bottles you use for EPA/DHA omega-3 supplements, because it can potentially migrate from contact materials into the encapsulated oil. In GOED's Randomized Testing Program we see that in about half of the encapsulated products globally there are quantifiable levels of BPA. I recommend that if you market your products in Europe, you at least measure, and know what the level of bisphenol A in your product is. It is also likely that contract manufacturers and brands will start searching for BPA-free food contact materials. There used to be what is called a specific migration limit (SML) for BPA of maximum 0.5 mg/kg, but with this new regulation this SML has been eliminated.

 Jenna – Just a comment on BPA sources. For people who are using epoxy-lined drums for transport, you may also want to check on that to make sure it's BPA free, in case of migration.

• EU Food Packaging and Packaging Waste Regulation (PPWR)

Gerard – In line with that, there is another European regulation that also just came into force (January 22, 2025), which is the European Packaging and Packaging Waste Regulation; the so-called PPWR (EC Reg 2025/40 – <u>link</u>). It was approved by the Council of Ministers in December, and by the European Parliament in April last year. It will be fully applicable 18 months after publications, so about mid-2026, This regulation has as its goal to make all packaging materials used in the European Union recyclable or re-utilizable, in order to reduce packaging waste, promote sustainability, and stimulate circular economy practices. In the regulation, which is quite long (<u>link</u>), there are requirements on, for example, the

minimum percentage of recycled materials that should be present in plastic packaging. There are also requirements for the quality of the recycled material. and the obligations that various value chain actors have, such as by materials producers, suppliers, importers, distributors, waste operators, etc.

You may want to have a look at it to see to what effect this has on your business, especially if you operate in Europe. The regulation has many implications, such as:

- Packaging materials will have to meet the PPWR regarding requirements and new design standards
- Collaboration between contract manufacturing & brands to align the packaging materials used
- Demands for materials documentation and traceability
- Potential for new logistic systems for the return of reusable materials and refillable packaging
- Effects on consumer perception
- Possibility to promote your circular business model
- Increased costs for material lifecycle management, but there may also be cost reductions when choosing other, cheaper materials or optimizing your packaging waste
- Innovations in reducing waste or reutilizing materials and product designs
- A need to inform or educate consumers about the recycling of packaging materials

There will be both new challenges and opportunities here. For sure, this will have a major effect on the European food product packaging business.

Some links to specific contaminants are also made also in this regulation. In this regulation there are new maximum levels (ML) of per/poly-fluoroalkyl substances (PFAS) specified. For example, there is an ML of 250 ppb for the sum of all quantifiable target PFAS. There are some other MLs for individual or subset PFAS. The EC indicates that there may be a new risk assessment in the future for the exposure of PFAS from food contact materials. A ML of 100 mg/kg for the sum of the heavy metals lead, cadmium, mercury and hexavalent chromium. And, as mentioned above, the use of BPA has now been banned for food contact materials. There is no word about phthalates in this regulation.

There is a very specific, interesting, note for those of you who participate in trade shows in Europe – the regulation says explicitly that the regulation doesn't prohibit the showing of packaging at trade shows that do not meet this new regulation, but you must make clear with a visible sign that such packaging is not for sale until it has been brought into conformity.

All Other Business (Jenna Ritter)

- Inclusion of optional testing for vitamins A, D and E in AOCS-GOED Nutraceutical Oils LPP (Tony Bimbo)
 - o Tony I contacted AOCS about including the vitamins in the AOCS-GOED Nutraceutical Oils Laboratory Proficiency Program (LPP) series. Oe of the requirements is that we come up with a list of recommended methods of analysis for vitamin A, D and E (tocopherols). I have got the USP-NF current method numbers, and the current European pharmacopoeia for cod liver oil current numbers. But these do not include methods for vitamin E, so I did a search, and found an ISO method for tocopherol and tocotrienols in animal and vegetable fats and oils. And there is an AOCS method for tocopherols and vegetable oils. I do not know how current these methods versions are. I also found a bunch of ISO methods for vitamin A and D, and also an AOAC method. So, I put a list together, and I'll send it to Gerard, to include in the minutes of this meeting. I need some feedback on what methods we would recommend for vitamin A, D and E. This is time sensitive because it's got to go through the AOCS bureaucracy and get approved at the annual meeting in April, so we can't delay too much longer.
 - o **Gerard** I will show those methods in the minutes, and also send a separate email to this committee, and we'll ask people then to provide feedback regarding the suitability of these methods. Tony, is that what you need?
 - o Tony Yes

Methods listing:

- ISO 6867-2000 Vitamin D by HPLC Vitamin D in Animal feeding stuffs
- ISO 14565-2000 Vitamin A by HPLC Vitamin D in Animal feeding stuffs
- ISO 20636-2018 Vitamin D by liquid chromatography-Mass Spec. Infant formula and Adult Nutritionals
- ISO 9936:2016 Tocopherol and Tocotrienol in Animal and vegetable fats and oils
- AOCS Ce8-89(97) Tocopherols in vegetable oils
- AOAC 20th ed 2016 Vol II 45.1.20 981.17 Vitamin D in Vitamin A and D concentrates by Liquid Chromatography
- AOAC 20th ed 2016 Vol II 45.1.20 982.29 Vitamin D in pet foods by Liquid Chromatography
- USP/NF (571) Vitamin A
- USP/NF (581) Vitamin D
- PhEur Version, 11.8. Cod Liver Oil Vitamins A and D

• Action item – Inform Tony or Gerard which of the listed methods for vitamin A, D and E (tocopherols) are suitable for EPA/DHA omega-3 oils, and what the current method numbers are (Gerard and Tony)

• MOH Update

Gerard – In the last meeting in December, we discussed the results of a meeting of the European Member States Expert Group that discussed the proposal for MLs on mineral oil hydrocarbons (MOH), in particular for MOAH. We now have a little bit of additional information, through one of our members through the French food industry that receives notices about what is happening in this expert group. The news about MOAH is that discussions are ongoing with apparently divergent positions among the EU Member States. We already heard that the application date for MOAH regulation has been postponed by one year, which is now set to enter into force on January 1, 2027, and with work continuing based on the so-called third option. This option 3 is where it says that the ML for MOAH for marine oils will be 10 mg/kg for fats and oils. There is some information for updates to MLs for other commodities (*contact Gerard if you would like to know more about these*). There has not been further discussion of marine oils as far as we know, so hopefully there won't be any proposal for a change to this proposed ML of 10 mg/kg.

We heard that there is no timeline for the publication day date of the regulation draft, and it probably won't happen before this summer. There will be at least one or two more expert meetings before a stakeholder consultation will be opened, where we can have another round of input if needed. and before the finalization of the text for a vote by the EU Council of Ministers. But it sounds like there is still some way to go before any agreement is found on how that final proposal will look like.

For MOSH, there is a draft recommendation for the monitoring of MOSH. There are some changes in what they call indicative values. These are not legal limits, but limits where the food authorities may start interacting with the food business operators when levels are considered too high.

Apparently, there is also some recognition by Member States that there is a lack of harmonized and robust analytical methods for all matrices, and a limited number of laboratories with sufficient analytical capacity. This is something we've known now for a long time.

Regarding food additives, discussions are also ongoing. There is a generic limit of 2 mg/kg being proposed, with exceptions, notably for emulsifiers.

This is the information we have to date. If anybody else has information from these expert meetings through their national authorities, please inform GOED. It is important for us to know what is going on.

• GOED newsletter survey

- Gerard A few days ago, we sent out a survey (<u>link</u>) about our GOED newsletter, The Current.
- Ellen Our newsletter that we send out every week is our main way of communicating with members, and we are just looking at ways we could possibly improve it. So, there's a short survey that we've sent out through our newsletter. We are also interested in hearing from the committees, just because you have different interests, or you know things that you want to know about, compared to our communications or regulatory committee. It is just us trying to gather information about what you do and don't like about the newsletter, to see how we can make it better.

• Technical publications notification

Jenna – We sent out with the agenda a document that contains a list of recent publications that may be relevant to the people on this call. They are all related to technical aspects of EPA and DHA. Lots of alternative sources other than anchovy, sardine, mackerel. There should be some interesting information in there for those of you who want to keep on top of the science out there.

Presentation:

"A Sneak Peek into GOED's Global Omega-3 Navigator: Regulatory and Technical" – Gaby Cortez – Regulatory and Technical Support Manager, GOED

A copy of the presentation will be uploaded to our GOED Presentations folder (<u>link</u>) after the meeting.

- Harry I just want to mention that the topics are going to be expanded over the coming months, for example with food additive information. And a bunch of other compilations we have started over the years, like label claims, compliance, and upper limits. Where can ethyl esters be sold? Where can triglycerides be sold? So, over time that type of information will be included in the Global Omega-3 Navigator as well. We would like to ask for feedback from all of you who will be using it. Please let us know if you find anything that is wrong. Please also let us know if you have information that belongs in one of the categories that we're we've populated here. I just have to say, Gaby has been working on this project for six months since she came on with GOED, and she has done a spectacular job. The result far exceeded my expectations. So much information is in this one place. So, a very nice job, Gaby.
- o Gerard Can all go members use this tool, and where can they find it?
- Gaby There is a tab for the global Omega-3 Navigator in the Member portal under Regulatory Information - <u>link</u>. In the Current we will have an official launch, where we will provide more information about it.
- o Ellen It is being introduced in the Current on Monday, February 3rd (<u>link</u>).
- Arnar Halldórsson (Lysi) It is a big effort to build up a database like that. We did that a couple of years ago for only European Union regulations and claims. I managed to find it, and it works like you showed. That is great.
- Ingjerd Lystad (Pharma Marine) I want to thank you for the presentation. It seems like an amazing tool for us.
- **Arnar** The important part of this database is its maintenance. How frequently do you plan to maintain it, and how reliable can it be?
- o Gaby Yes, that is a good question. We actually have a meeting about that today.
- o **Arnar -** You could, for example, have on the top the latest update, or the date of the latest updates. Perhaps you can have a list of what was updated. Then you know what you did or what is new. That might be helpful. If you have not thought of that already.
- o **Gaby** We received a similar comment from somebody on the Regulatory Affairs Committee and we are discussing how to best address that because you're right. You know, the maintenance is going to be a challenge, there is no doubt. It would be good if the user could understand when the information was added. Right now, we are thinking about an additional column next to the information, so that you know when it was entered.
- o **Arnar** I will compare your database to our database with the European Union. If I find any discrepancy, I will let you know.
- o **Gaby** Thanks.

End of meeting.

Summary of Action Items

- Action item Include the proposed text on the calculation of five other omega-3 fatty acids in the Guidance Documents (Gerard Bannenberg, GOED)
- Action item Inform Tony or Gerard which of the listed methods for vitamin A, D and E (tocopherols) are suitable for EPA/DHA omega-3 oils, and what the current method numbers are (Gerard and Tony)

Date of next meeting

• The next Technical Committee meeting will be scheduled for Thursday, March 13th, 2025.

USEFUL LINKS:

- Useful documents that the committee has discussed can be found in the Technical Committee folder. You can upload any material there yourself as well: <u>https://drive.google.com/drive/folders/0B-5CurmVIvvETm1Wd29xemU5YVU</u>
- o Past minutes can be found here:
 - 2025 https://drive.google.com/drive/folders/1st1PlkU7Z0_3Phy4uya_ucmc34ThuWrG?usp=drive_link
 - 2024 https://drive.google.com/drive/folders/16WcCbtwh NY09cnx-pEpnANbubBv7Wmo?usp=drive_link
 - 2023 https://drive.google.com/drive/folders/1Q_aJTzxZL106KkZJUkgrkLT2MdgDiEXh?usp=share_link
 - 2022 https://drive.google.com/drive/folders/1Pt8CJafBCjIYaLZF0ZJ08csPqlzW5XaC?usp=sharing
 - 2021 https://drive.google.com/drive/folders/1VGy-t4TuWtDUB30jU98unIxWYzpnZuNj?usp=sharing
 - 2020 https://drive.google.com/open?id=1olF0Ab9UeGO_VaQpSshICS3xn0V8IiLK
 - 2019 https://drive.google.com/drive/folders/0B0usR2nagMSpSU1aaTR6Ty0yTE0
 - 2018 https://drive.google.com/open?id=11XXmBgN3F9XwZnXKxqq0hwC-oLZl9rc_
 - 2017 https://drive.google.com/drive/folders/0B6uJWj5y9FY9NDRRS2lVdUQ1ZWs
 - 2016 https://drive.google.com/drive/folders/0B6uJWj5y9FY9UVZpU3NLejBIMEk
- o GOED Presentations GOED Presentations (goedomega3.com)
- <u>o GOED Newsletters</u>: If you do not receive newsletters from GOED, please sign up since this is our best way of communicating with members. Here is the link: <u>https://goedomega3.com/members/subscribing-goed-current</u>