GOED Technical Committee - Minutes

Date: December 19, 2024

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

Jenna Ritter (*chair* – Nature's Way of Canada) Yutong Wang (Nutrasource/SGS)

Guowen Yang (Kinomega) Tina Vestland (Golden Omega)

Geir Frode Olsen (Epax Norway/Pelagia)

Tony Bimbo (International Fisheries)

Lilian Thiaux (Olvea)

Meagan Eggebeen (Amway)

Mina Fakhary (Pharmavite) Eline Verbaanderd (Friesland Campina)

Katrina Bartley (Nutrasource) Haraldur Sigurjónsson (Lysi)

Kenny Sharp (dsm-firmenich) Marita Buarø (GC Rieber/Vivomega)

Viorel Marculescu (MBP Solutions)

Roberto Valenzuela (Innocon)

Gerhard Kohn (Vesteraalens)

Anthony Bible (Wiley Companies)

Tim Johanek (Carlson Laboratories)

Brad DaDalt (Jamieson Laboratories)

Ingjerd Lystad (Pharma Marine)

Sunil Choudhary (OmegaBrite)

Vibeke Blondal (BASF)

Guy Ben-Zvi (Omega-3 Galil)

Roger Pettersen (Holtermann)

Fernando Miranda del Solar (Austral Group)

Magdalena Sobieska-Pietrzak (GC Rieber)

Sonia Casanova (Copeinca)

Helen Albans (Croda)

Senya Joerss (Trident Seafoods)

Luke McPherson (Mara Renewables)

Rafa Gracia (Solutex) Agata Szygula (TASA) Huw Watkins (EuroCaps) Arnar Halldórsson (Lysi)

Hyun-Ah Kim (Nutrasource/SGS)

Andrew Jenkins (Lipid Analytical Laboratories)

Christine Krumbholz (KD Pharma)

GOED Staff:

Gerard Bannenberg (GOED)

Gaby Cortez (GOED)

Harry Rice (GOED)

Ellen Schutt (GOED)

Guests:

Justin White (Nuseed)

Absented:

Chris Gearheart (GOED)

Johannes Kraft (Evonik)

Claus-Michael Brieber (Henry Lamotte Oils)

Chintan Shah (WR Grace)

Inge Bruheim (Rimfrost)

Sedanur Civil (EasyVit)

Roberto Fronzoni (KD Pharma)

Frank Möllering (NutriSwiss)

Ilke Balci (EasyVit)

Joan de Jong (Bioriginal)

Michelle Stout (Amway) Christine Bousses (Fermentalg)

Lina Cekaite (Aker Biomarine)

Invitees for this call:

Jorge Alberto Rodríguez González (CIATEJ, Zapopan, Jalisco, México) Hiram Guerrero (CIATEJ, Zapopan, Jalisco, México)

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
 - Kenny Sharp (dsm-firmenich) I am an analytical chemist with dsm-firmenich. I have worked with Jennifer May for about eight and a half years now, after about ten years in pharma. We run all kids of projects method development, process development, contaminants. I am really looking forward to contributing.
- Members who have left the committee:

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Monograph/Pharmacopeia Updates (Gerard Bannenberg - GOED)

- Update of Guidance Documents Quantification of other omega-3 fatty acids
 - o **Gerard** This is a follow-up of the discussion we have had in the past few meetings regarding the quantification of omega-3 fatty acids and the AOCS GOED Nutraceutical Oils LPP. While the Guidance Documents (<u>link</u>) 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. Since our discussion, some members have asked us what the most appropriate procedure is to determine the content of these fatty acids, when only certified reference standards are available for EPA and DHA. While it is not necessary to do that when determining Total Omega-3 content, this guidance is meant to be informative for those members that do want to

determine the content of the individual fatty acids. I would like to ask you to review the proposed text (*included in the documentation for this meeting*) and let me know if there are any suggestions for improvement or edits. We will come back to this for approval at our next meeting.

• **Action item** –Technical Committee members to review proposed addition to the Guidance Documents on the calculation of five other omega-3 fatty acids, and send comments to Jenna or Gerard (**Technical Committee members**)

<u>Legislative Updates (Gerard Bannenberg)</u>

- EFSA open consultation on characterization of microbes used in the food chain
 - Gerard EFSA just launched a public consultation about a draft document entitled "Guidance on the Characterization and Risk Assessment of Microorganisms used in the Food Chain" (link) The deadline for comments is February 7, 2025. The final document is scheduled to be published in June 2025. This guidance document is of relevance to GOED since it also mentions DHA- and EPA-producing microorganisms such as *Schizochytrium*. EFSA refers to "microalgae and other protists". The document explains how to make and evaluate taxonomic assessments, as well as consider the different aspects of food safety of microorganisms used to produce food or that are present in food. It also addresses safety aspects of genetically modified microorganisms. Have a look, as there is a lot of detailed information in this document for those who are interested in microorganisms. It is interesting and important to understand how the EU interprets what is needed for the assessment of food safety.
- Update on state of development of Codex Standard for Microbial Omega-3 Oils (Harry Rice, GOED)
 - O Harry As you likely know, at the end of November, GOED's proposal for new work to develop a standard for Microbial Omega-3 Oils was officially adopted during the 47th session of the Codex Alimentarius Commission meeting. Gerard had the privilege of being there alongside our Codex consultant David Piñeda. So now that the proposal has been officially accepted, the electronic working group (EWG) can move forward without any kind of fear that its work will stop. The EWG is chaired by the US, and co-chaired by China, who will continue the work on revising the draft standard for discussion at the next CCFO meeting, which takes place in February of 2026. The EWG started its work in August, when a draft standard was circulated to the EWG participants. That draft standard is the same that GOED submitted alongside its Proposal for New Work that was discussed at last February's CCFO

meeting (Kuala Lumpur, Malaysia). Comments from the EWG were accepted until the end of October. That was after two deadline extensions. GOED met with the US Delegation to discuss the comments. We have since provided written feedback to the US Delegation on comments that the EWG received. We are due to meet the US delegation again after we come back from the holidays for further discussion. I suspect that a second draft proposed standard will be released by the end of January 2025. It is not clear when the deadline for comments is going to be. I suspect in March. The idea now is that there will be three rounds of comments, and then a final draft standard will be submitted to the Codex Secretariat, which in turn will be posted to the Codex website. The final draft has to be posted within three months of the next CCFO meeting. I think things are moving along as expected. It is turning out to be a lot more work than we anticipated, but a lot has changed since we first submitted the proposal for new work. I am amazed at what we have learned.

- Ellen Schutt (GOED I just have a question about the process. When the next call for comments comes, or the next standard is released, does it then go to all the Codex delegates – is that who the audience is? Are we receiving a crazy number of comments?
- O Harry It actually goes to the EWG members. There was an invitation during the summer, asking who wanted to be part of the EWG, and you had to register for that. I can't remember how many participants there are. There were only six countries that submitted comments in response to the first draft proposed standard. In the EWG, there is not a crazy number of comments that have to be addressed. But those "crazy" number of comments will come at the next CCFO meeting, when all the people that decided not to participate in the working group are going to wake up and say, "this doesn't work". It happened multiple times during the creation of the Codex Standard for Fish Oils.
- Gerard I just like to add that we rely a lot on the input from our members. So, whenever
 we ask for information and you have any, it is very helpful for us to receive that. You will
 remain updated on the progress, also through the Current.

• EFSA draft Scientific Opinion on complex organoarsenic compounds in food

O Gerard – EFSA just released a new Scientific Opinion on organoarsenic species in food, this time about a category called "complex organoarsenic compounds" (link). In our recent meetings we have been looking at EFSA's Scientific Opinion on the small organic arsenic species monomethyl arsonic acid (MMA(V)) and dimethyl arsinic acid (DMA(V). EFSA has expanded its risk assessment to additional species that include arsenobetaine, arsenosugars and arsenolipids. This latest Scientific Opinion concludes that there is no health concern with regard to arsenobetaine and arsenosugars exposure through food consumption. Not enough information was available to evaluate the health risk from arsenolipids exposure. That is interesting because there are publications indicating that arsenolipids may be the major form in which arsenic is found in fish oils.

All Other Business (Jenna Ritter)

Evaluation of method ISO 12966

- O Gerard In August we invited FOSFA (link) to present about their work (link). They pointed out that significant differences in the testing results of EPA and DHA content of omega-3 oils are reported between parties, and asked GOED for input. This is relevant because it involves hundreds of testing laboratories of producers, shippers and ports, which all have to use the same method, ISO 12966. In order to give a coherent reply, we would like to evaluate this method in the same systematic way that we did in the beginning of this year for two other methods; AOCS Ce 1b-89 and AOAC 996.06 (see evaluations link). We will reach out in January to those Technical Committee specialists with experience in EPA/DHA quantification that have participated in the previous method evaluation, to see who is interested in evaluating this method. We will use the same pre-specified criteria to evaluate the suitability and possible defects of ISO 12966 for the quantification of EPA and DHA in omega-3 oils.
- Geir Frode Olsen (Epax Norway) I have not read this method, but any method that does
 not mention omega-3 in the title, cannot be used. But we will see it will be interesting to
 read it.
- Gerard That is a good point, because the objective of this evaluation is to show in a formal
 way where any flaws in this method may be found. Or if the method is suitable under
 particular circumstances, or for specific oil types.
- Action item Initiate method evaluation of ISO 12966 (Gerard and Jenna)

CEFIC

O Gerard – CEFIC is a major business organization for the European chemical industry (link). I would like to ask if anybody on the Technical Committee knows about work carried out within CEFIC on mineral oil hydrocarbons (MOH). Or has any contacts within CEFIC to explore what activities regarding MOH are being undertaken. Please let Jenna or Gerard know if you do.

MOH regulations update

Gerard – Yesterday, we published a News Alert (<u>link</u>) about the results of a meeting held last week by the European Member States Expert Group, which discussed upcoming mineral oil hydrocarbon (MOH) regulations. Lilian Thiaux (Olvea), who is a member of the

Technical Committee, and present, updated us two days ago about these developments, which are as follows:

First, Member States did not reach an agreement on the text of the proposed European Commission regulation for MOH in the European Union (EU). The text will not be on the agenda for the next Expert Group session in February 2025, and at least one additional discussion round is expected (dates are yet to be scheduled).

What was decided was that the enforcement date has been postponed to January 1, 2027.

Regarding maximum limits (ML) on MOAH, the Commission is still working on the following option (referred to as Option 3). Note that this has not changed since the draft (referenced above) was released earlier this year.

Product category	Maximum limits and date of enforcement
Marine oil and essential oil	10,0 from 01/01/2026* 5,0 from 01/01/2030
Food supplements	10,0 from 01/01/2026* 5,0 from 01/01/2030

^{*} to be postponed to 01/01/2027

GOED is currently seeking confirmation on the discussions that were held about marine oils and food supplements. Also to be confirmed is the ML of 2 mg/kg for blends of oils of different origins.

Importantly, the meeting did lead to a decision that MOAH thresholds will apply to crude oils intended for refining (but not to what are called "intermediary products"). GOED will seek further information about what this means in practice for the importation of crude fish oil batches intended to be refined in the EU.

Regarding MOSH, no definitive position was found by the Expert Group and remains a point of discussion. It appears that the Indicative limit of 15 mg/kg (total MOSH) would remain.

Finally, a new stakeholder consultation will take place after the Member States agree on a final draft. GOED recommends that members participate in this consultation, if possible, through their national representatives or any European trade associations of which they are a member.

It is also worth mentioning that the European consumer organization FoodWatch recently published a press release contesting the discussed limit values (<u>link</u>). FoodWatch's influence was one of the factors that kickstarted the original discussions about the need for setting regulations for mineral oil contamination of food in Europe. It is currently unclear to what extent the organization's opinion will influence the current Member States' discussions.

- **Lilian Thiaux** (**Olvea**) Just something to highlight The potential upcoming limits for marine oils and food supplements until now is still 10 mg/kg for January 2027 but maybe it will be reviewed. Nobody knows exactly, so let's wait for the final draft.
- **Gerard** Thank you.

• Technical publications notification

o **Gerard** – Together with the agenda, we have included a listing of the technical publications published in the past five weeks. Have a look to see if there is anything of interest to you.

Presentation:

"Measuring the hydrolysis of omega-3 fatty acid esters; Selecting biocatalysts for improved EPA and DHA purification" – Jorge Alberto Rodríguez González – Industrial Biotechnology Unit, Research Center for Technological Assistance and Design (CIATEJ), Zapopan, Jalisco, Mexico - link)

A copy of the presentation will be shared with the committee after the meeting.

Q&A

- o **Gerard** What are the typical volumes you produce in your pilot plant?
- Jorge About 15 kg per hour. This pilot equipment does not have the same vacuum, and the purity of the EPA-EE and DHA-EE is not the same as on the laboratory scale. We need to work to improve the vacuum of this pilot equipment.
- Gerard What are your plans for the near future in which direction would you like to develop?
- O Jorge We would like to develop structured lipids, using these purified ethyl ester fractions. As shown in the presentation, we can produce structured lipids with a probe in some specific position. Gastro-intestinal lipases only hydrolyze and esterify at standard positions in triacylglycerols. It is possible to move EPA or DHA into the second position and use medium- or short-chain fatty acids for the other positions. With this we could achieve a 2-

monoglyceride containing this polyunsaturated fatty acid, which can be absorbed in the organism. We can achieve trans-esterification using the fatty acid-ethyl esters and the triglyceride containing medium- or short-chain fatty acids. There are not many lipases that can do this.

End of meeting.

Summary of Action Items

- **Action item** –Technical Committee members to review proposed addition to the Guidance Documents on the calculation of five other omega-3 fatty acids, and send comments to Jenna or Gerard (**Technical Committee members**)
- Action item Initiate method evaluation of ISO 12966 (Gerard and Jenna)

Date of next meeting

• The next Technical Committee meeting will be tentatively scheduled for Thursday, January 30th, 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: https://drive.google.com/drive/folders/0B-5CurmVIvvETm1Wd29xemU5YVU
- o Past minutes can be found here:
 - 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
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 - 2021 https://drive.google.com/drive/folders/1VGy-t4TuWtDUB30jU98unIxWYzpnZuNj?usp=sharing
 - 2020 https://drive.google.com/open?id=1oIF0Ab9UeGO_VaQpSshICS3xn0V8IiLK
 - 2019 https://drive.google.com/drive/folders/0B0usR2nagMSpSU1aaTR6Ty0yTE0
 - 2018 https://drive.google.com/open?id=1lXXmBgN3F9XwZnXKxqq0hwC-oLZl9rc
 - 2017 https://drive.google.com/drive/folders/0B6uJWj5y9FY9NDRRS2IVdUQ1ZWs
 - 2016 https://drive.google.com/drive/folders/0B6uJWj5y9FY9UVZpU3NLejBIMEk
- o GOED Presentations GOED Presentations (goedomega3.com)

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