



GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3S

Regulatory Affairs Committee Agenda

Date: Tuesday, 18 June 2024

Start Time: Click [here](#).

AGENDA ITEM	Old* or New** Issue for This Meeting?
Introducing Gabriela Andrea Cortez Ramos – GOED Regulatory and Technical Support Manager	New
China - GB 1903.66-2024 National Food Safety Standard Nutritional Fortification Substance Docosahexaenoic Acid Oil (Fermentation) - This standard was issued on 8 February 2024 and replaces GB 26400-2011 National Food Safety Standard Food Additive Docosahexaenoic Acid Oil (Fermentation Method) and comes into force 8 August 2024. GB 1903.66-2024 食品安全国家标准 食 - English Translation - Mara has a customer struggling to convince their China office that their refined algal oil produced using Mara crude oil meets this standard. - The issues seems to be the note at the bottom of table 2 where the specification resides which indicates, “<i>Note: Commercialized docosahexaenoic acid oil products use docosahexaenoic acid oil that meets this standard as raw materials, and food necessary for the process can be added. The quality, scope and usage of raw materials and/or food additives as auxiliary materials comply with the corresponding national food safety standards.</i>” - The interpretation by the customer’s office in China is that in the above note: - The “commercialized DHA oil product” would be the refined oil exported to China for incorporation into a food product - The crude oil is a “raw material” for the commercialized DHA oil, and thus must meet this standard. - To be discussed by this committee is whether or not you think that is a correct interpretation or if you think it’s possible that the “commercialized DHA oil product” is that which is sold to consumers and that the oil that goes into the product needs to meet the standard (i.e. the refined oil)?	New
UK – Risk Categorization of Fish Oils from Low to Medium	New



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• On 22 May 2024, CRN UK informed GOED that on 30 April 2024, the UK established new border controls, with the health certification of goods entering being dependent upon the risk categorization for those goods. • See Import risk categories and inspection rates for animal and animal product imports from the EU to Great Britain: summary tables. • Fish oils had been categorized as low risk for both bulk and finished product imports, which meant that the imports had to be pre-notified, but they did not require a health certificate or border check. Without notice, the UK changed the categorization from low to medium risk for all fish oils originating from species of the following families: Scombridae, Clupeidae, Engraulidae, Coryfenidae, Pomatomidae or Scombresosidae. The UK considers these families to be associated with histamine. This meant that fish oil (both bulk and finished products) originating from species from those families that is imported to the UK from either EU or non-EU countries would require a health certificate. Any company importing fish oil to the UK from the EU were suddenly faced with increased costs and delays. • CRN UK asked GOED if we had any data on the presence of histamine in fish oils from fish species from the aforementioned families in order to argue a return to a low risk categorization. They also asked if we had data on the approximate ratio of fish oil from the mentioned families versus fish oil from other families. GOED replied with information. The details will be provided in the minutes. • On 4 June, CRN UK informed GOED of the following positive news from the UK authorities: ○ "Thank you for sharing this evidence. The risk categorisation of fish oil from species associated with histamine intended for human consumption will be reviewed at the next risk categorisation review meeting in August. ○ We are temporarily placing fish oil intended for human consumption from species associated with histamine in the BTOM low-risk category, both for non-EU and EU imports. We have informed PHAs of this and will soon be updating the relevant gov.uk pages. ○ For composite products capsuled in gelatine, the low-risk categorisation is for the fish oil component only. These products may still be medium risk for certain non-EU imports. The risk categorisation of gelatine for human consumption is outlined in Table 2e of the BTOM non-EU risk category summary tables." • Harry asked CRN UK why the sudden change in risk categorization. According to the authorities, there was no change made, just clarification. Apparently, fish and fishery products from the families associated with histamine have always been considered medium risk, but this had not been disseminated across all the relevant guidance information, so they added the notes and did not consider prior warning necessary. While fish oil had been excluded in the past, whoever provided the text for the notes was apparently unaware of the science and therefore did not include the exemption.	
China – Facility Registration Requirement • Does anyone have additional information to share?	Old



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China – Exporting Algal Oil from Germany to China After the last meeting, Christine wrote, “Concerning the topic China – Exporting Algal Oil from Germany to China, I have checked with my colleague, and in our state, the responsible authority is the Landwirtschaftskammer (Agricultural office). However, it may be different in other states within Germany.”	Old
EU – DG SANTE - The draft audit report has not been released yet, so we cannot continue our discussion on food additives (i.e. antioxidants). - However, on a related (EU Hygiene Regulations) topic, GOED has heard that some companies in Peru are using one line (with cleaning in-between) to process both fish oil for human consumption and fish oil for non-human consumption. Per the 20 May 2022 GOED Current, GOED was under the impression that the EC allows for the use of only one production line provided that all fish oil produced is for human consumption and a gatekeeper is implemented at the point where the fish are discharged to ensure that the raw material is processed within 36 hours of capture and the Total Volatile Basic Nitrogen (TVB-N) value is below 60 mg of nitrogen/100 g. Has anyone heard about DG SANTE permitting the use of only one line to process fish oil for human and non-human consumption, provided there is cleaning in-between?	Old
EU – For Fish Oil, Does the Fish Species Need to be Declared on the Label? Does anyone have further thoughts on this topic?	Old
US – For Fish Oil, Does the Fish Species Need to be Declared on the Label? In the previous minutes, I (Harry) mentioned that there is a good argument for not having to label the fish species from which the fish oil originates. 21 CFR 101.4 (b) (14) could be viewed as conflicting with that opinion. What do committee members think?	Old
FSANZ-Infant Formula Update The Food Standards Australia New Zealand (FSANZ) Board approved Proposal P1028 – Infant Formula on 4 June 2024, and has notified the Food Ministers’ Meeting of the decision. The Proposal is now being considered by the Food Ministers who are responsible for final acceptance, amendment or rejection of the proposed amendments to the Australia New Zealand Food Standards Code (the Code). The final decision is expected by mid-August 2024.	New
India – Crude Fish Oil Standard	Old
US – Cardiovascular Claims	Old
GOED Intake Recommendations	Old
US – Organic	Old



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<u>EU – Mineral Oil</u>	Old
On Hold Pending Additional Information and/or Time to Address	
• Taiwan – Fish Oil Label Warning • Indonesia – Warning on Supplements • Labelling of the various omega-3 ingredients (TGs, EEs, named oils, algal oils, etc.) in different geographies • India – Trans Fat • Australia - Compositional Guideline DHA-rich oil derived from microalgae <i>Schizochytrium</i> sp. • United States - Export Certification of Encapsulated Fish Oil for Human Consumption • CCFL – Sustainability Claims • Europe – EC Initiative proposing maximum levels for vitamins or minerals that may be added to food supplements	

*For old issues, topic specific minutes from past meetings can be viewed by clicking on the agenda item. Bullets may be included providing additional information relevant to the forthcoming discussion.

**For new issues, bullets are provided with background information. If the issue was discussed previously, but not in recent months, a link to past meeting minutes will be included.

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