GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3S

Dr. Douglas Balentine
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October 26, 2018

RE: Agenda Item 7 - Proposed Draft NRV-NCD for EPA and DHA long chain omega-3 fatty acids

Dear Dr. Balentine:

The Global Organization for EPA and DHA Omega-3s (GOED) is an association of processors, refiners, manufacturers, distributors, marketers, retailers and supporters of products containing eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) omega-3 fatty acids. GOED's membership represents a broad range of businesses, from small entrepreneurs to multinational food companies. The Organization's objectives are to educate consumers about the health benefits of EPA and DHA and to collaborate with government groups, the healthcare community and the industry on issues related to omega-3s, while setting high standards for our business sector.

For your consideration when drafting the United States' comments for the 40th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) to be held in Berlin, Germany from 26-30 November 2018, GOED is providing its comments on the Report of the electronic Working Group (eWG) on Establishing an NRV-NCD for EPA and DHA, Codex document CX/NFSDU 18/40/8 in relation to Agenda item 7 - Proposed Draft NRV-NCD for EPA and DHA long chain omega-3 fatty acids,

4.1. Recommendation 1

> *Taking into consideration that no consensus has been reached on quality of evidence collected in support of the EPA and DHA effect on CHD mortality, to postpone further discussion of the NRV-NCD for EPA and DHA until new convincing/generally accepted evidence becomes available.*
>
> *The Committee might also want to seek clarification from NUGAG on their definition of CHD death and cardiac death in the systematic review of RCTs*

GOED supports the recommendation to postpone further discussion on this agenda item, despite our opinion that the totality of the available scientific evidence supports the adoption of an NRV-NCD for EPA+DHA for inclusion in the *Guidelines on Nutrition Labelling (CAC/GL2-1985).*[1]

It's clear from the consultations and discussions over the last three years that there is a lack of necessary consensus to adopt an NRV-NCD EPA+DHA. While GOED supports the postponement of further discussion, there should be a clear and reasonable definition of the threshold of evidence

[1] http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCAC%2BGL%2B2-1985%252FCXG_002e.pdf

required to resume future discussion. To this end, GOED's support of this recommendation is tied to its support of Recommendation #4 – "To consider if discussion needs to be initiated on reviewing criteria of the evidence that meets definition of convincing/generally accepted." In addition, GOED suggests discussing the use of a variety of evidence grading terminologies in order to accommodate a wider range of reviews.

GOED also supports seeking clarification from NUGAG on its definition of CHD death and cardiac death in the systematic review of RCTs published as "Omega-3 fatty acids for the primary and secondary prevention of cardiovascular disease[2]". It is GOED's opinion that among the potential reasons for the risk reduction for CHD deaths not reaching statistical significance is that relevant fatal CHD events were missed due to its definition of CHD mortality. Curiously, NUGAG adopted a prioritization scheme for CHD mortality in its review of RCTs that differed from its review of the observational evidence, presented at CCNFSDU39, but so far not published.

4.2. Recommendation 2

> *To initiate new work on revision of the General Principles addressing the following:*
> *• Amending item 3.2.2 to account opinions of RASBs that considered not to set intake reference values for nutrients reviewed for establishing an NRV-NCD.*

GOED supports this recommendation, because it includes a review of the totality of the available scientific evidence and the omission of opinions of RASBs who did not establish reference intake values introduces bias into the process. Thus said, should consideration of reviews from RASBs in which a reference intake value was not established require amending item 3.2.2, then GOED supports such change.

Since this issue is not specific to EPA+DHA, the work in this recommendation can be pursued regardless of the outcome of recommendation #1.

4.3. Recommendation 3

> *To continue using the terms convincing, generally acceptable, probable, possible and insufficient as defined in the Joint FAO/WHO Expert Consultation [6] for the purpose of establishing NRV-NCD according to the General Principles.*

GOED supports this recommendation. The use of the criteria convincing, probable, possible and insufficient are acceptable for use, but the use of only GRADE-based descriptions is too restrictive in that it may eliminates the ability to consider reviews from other RASBs, who contribute to the totality of the available scientific evidence.

While GRADE provides a way to evaluate the strength of evidence for each type of study, it does not provide a good way to combine these assessments. In addition, GRADE ignores all other evidence,

[2] https://www.ncbi.nlm.nih.gov/pubmed/30019766

including the effect on biomarkers or plausible mechanistic explanations. The strength of GRADE over other systems is that it separates the strength of evidence from the strength of recommendation, and leaves these decisions to different groups of people, with different expertise. Focusing on only strength of evidence misses the point, and leaves the recommendations in the hands of data analysts instead of the public health experts and risk assessors, who are the ones with the necessary expertise to evaluate the balance between risks and benefits of any given intervention.

Since this issue is not specific to EPA+DHA, the work in this recommendation can be pursued regardless of the outcome of recommendation #1.

4.4. Recommendation 4

> *To consider if discussion needs to be initiated on reviewing criteria of the evidence that meets definition of convincing/generally accepted.*

GOED supports this recommendation as mentioned previously in its comment to Recommendation #1.

The first item of Section 3.2.2 of the Annex to CAC/GL 2-1985 acknowledges and accommodates a range of evidence grading methodologies by accepting "relevant convincing," "generally accepted," "or a comparable level of evidence under the GRADE classification." Without accommodation of a variety of generally accepted evidence grading terminologies, only evidence evaluated using GRADE will ever enter deliberations. Given that GRADE has not been globally adopted by all relevant RASBs and does not reflect all elements of a cause and effect relationship, the restriction to only GRADE-based evaluations effectively eliminates consideration of any other RASB relevant evidence review and curtails an evaluation of the totality of the available scientific evidence.

Since this issue is not specific to EPA+DHA, the work in this recommendation can be pursued regardless of the outcome of recommendation #1.

In closing, GOED appreciates your consideration of the above comments.

Sincerely,

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