GOED OMEGA-3

GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3

Establishing a DRI for EPA+DHA: Update on GOED Activities

September 28, 2020: While 2020 has certainly not been a normal year and the ability to further the advancement of a dietary reference intake (DRI) for EPA and DHA in the US and Canada has been hampered by COVID-19, GOED has still been working behind the scenes to gather intelligence and determine potential next steps to moving the DRI process forward.

The primary challenge continues to be the lack of transparency in the process at many levels. As reported last month, part of the challenge is the unclear funding mechanism with which to execute the process.

In addition, the Federal DRI Committees from Canada and the US changed the landscape when they introduced the concept of using chronic disease risk reduction – rather than only nutrient deficiency – as a potential path to achieving a DRI. While this change had been in the works for some time, the specifics of how to implement the guiding principles remain murky at best.

Also, opinions are mixed on whether it makes sense to pursue a political route, which could include a lobbying effort, for example, and drives the process through legislative channels, or a scientific route, which would involve securing funding to conduct additional research to fill in perceived scientific gaps.

A timeline on the whole DRI process from 2002 to present is included at the end of this document but here's an update on recent activity.

Late last year GOED participated in a Canadian omega-3 DRI workshop organized by the Canadian Nutrition Society, Health Canada and Drs. David Ma and Richard Bazinet (who presented on the workshop at GOED Exchange 2020). The workshop was organized to discuss the guiding principles to establish DRIs based on chronic disease risk reduction, stimulate discussion about the strength of the omega-3 scientific evidence, and consider next steps. The proceedings of the workshop will be shared in an upcoming publication.

For some time, there had been discussion about sponsoring a similar DRI workshop in the US In February of this year, GOED had a discussion with The New York Academy of Sciences to inquire about having it coordinate the workshop. However, upon further discussion with GOED's Regulatory Affairs Subcommittee, the consensus was that GOED shouldn't plan a workshop yet, because more information was needed (i.e., "Who would the workshop target? What does the roadmap look like to establishing a DRI?"). The GOED board agreed that additional information gathering was a logical next step.

Shortly after that, GOED learned of a proposed plan to review all macronutrients and their constituents (presumably including EPA and DHA as part of "fat"), but the project is contingent on securing $10 million in funding over five years. A timeline has not been established and the fact that this is an election year in the US — coupled with COVID-19 — has further slowed

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activity.

In an attempt to gain a better understanding of the best route to pursue, GOED has had conversations about potential next steps with several key GOED members, as well as — among others — the Council for Responsible Nutrition (CRN) and the International Life Sciences Institute of North America (ILSI NA).

CRN is a trade association that engages in lobbying, so we wanted to learn what the political route might look like. We discussed the idea of doing an omega-3 briefing during a meeting of the Dietary Supplement Caucus (DSC), a bipartisan forum for the exchange of ideas and information on dietary supplements in Congress. The DSC sponsors regular luncheon briefings on Capitol Hill and CRN agreed that this is an important subject to include in a future briefing. While we intend to pursue this meeting in the future, due to COVID-19, there are no briefings going on at this time.

To assess the scientific path, GOED has had a number of discussions with ILSI NA, the most recent taking place at the end of August, to determine if there is a gap in the scientific evidence that would benefit from a targeted project. A project was not identified, but GOED plans to reconnect with ILSI NA after the manuscript of the workshop proceedings from the above-mentioned Canadian omega-3 DRI workshop are published. The thought is that the manuscript may provide a springboard for further ideas, particularly if it includes a gap analysis.

It's worth noting that an absence of sufficient scientific evidence for an omega-3 benefit in primary prevention will likely be considered a gap, a point made by Dr. Patsy Brannon, who was a member of the DRI review committee for sodium and potassium, during the webinar "Public Health Implications of Recent Clinical Evidence on Omega-3 Fatty Acids and Cardiovascular Disease," Part 2, which took place this past June.

While GOED remains hopeful that the funding will be secured to review the macronutrients, including fat and its constituents (i.e., EPA and DHA) and a timeline will be established in the near future, at this point we are monitoring the discussions and continuing to gather additional information.

The DRI timeline – background and important milestones:

- 2002: The Institute of Medicine (IOM), now known as the National Academy of Medicine (NAM), concluded that insufficient data were available to define DRIs for EPA or DHA.
- May 2008: GOED sponsored "A Workshop on Assessing the Environment for Regulatory Change for EPA and DHA."
- The publication "Assessing the environment for regulatory change for eicosapentaenoic acid and docosahexaenoic acid nutrition labeling" was published soon thereafter.

- June 2008: ILSI NA sponsored a workshop to consider whether the body of evidence specific to the major chronic diseases in the United States — coronary heart disease (CHD), cancer, and cognitive decline — had evolved sufficiently to justify reconsideration of a DRI for EPA+DHA.
- The publication "Towards Establishing Dietary Reference Intakes for Eicosapentaenoic and Docosahexaenoic Acids" was published soon thereafter.
- September 2009: GOED, along with eight other associations/organizations, filed a Citizen Petition requesting the IOM's Food and Nutrition Board (FNB) to convene an expert panel to update DRIs for EPA and DHA.
- July 2013: GOED nominated EPA and DHA for DRI review.
- August 2014: EPA and DHA, along with three other nutrients, were selected as top priority nutrients for DRI reviews.
- January 2017: "Options for Basing Dietary Reference Intakes (DRIs) on Chronic Disease Endpoints: Report from a Joint US-/Canadian-sponsored Working Group" ("Options Report") was published.
- June 2017: GOED's Executive Council on Education and Outreach (ECEO) commissioned a feasibility study to consider the Options Report and determine if sufficient science exists to establish DRIs for EPA and DHA.
- August 2017: "Guiding Principles for Developing Dietary Reference Intakes Based on Chronic Disease" was published.
- February 2018: The ECEO's commissioned feasibility study is completed and concludes additional research is likely necessary. Keep in mind this report was completed prior to the publication of ASCEND, VITAL and REDUCE-IT.
- February 2019: "Report of Activities Related to the Dietary Reference Intakes from the Joint Canada-US Dietary Reference Intakes Working Group" was published.
- December 2019: Canadian Omega-3 DRI Workshop takes place.
- February 2020: The National Academies of Sciences, Engineering, and Medicine released a new resource to help explain the expansion of the DRI model.