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VIA ELECTRONIC SUBMISSION

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Re: Proposed draft NRV-non-communicable disease (NCD) for EPA and DHA long chain omega-3 fatty acids (Document CX/NFSDU 16/38/8)

The Council for Responsible Nutrition (CRN)[1] is the leading trade association for the dietary supplement and nutritional products industry, representing manufacturers of dietary

[1] The Council for Responsible Nutrition (CRN), founded in 1973 and based in Washington, D.C., is the leading trade association representing dietary supplement and functional food manufacturers, marketers and ingredient suppliers. CRN companies produce a large portion of the functional food ingredients and dietary supplements marketed in the United States and globally. Our member companies manufacture popular national brands as well as the store brands marketed by major supermarkets, drug stores and discount chains. These products also include those marketed through natural food stores and mainstream direct selling companies. CRN represents more than 150 companies that manufacture dietary ingredients, dietary supplements and/or functional foods, or supply services to those suppliers and manufacturers. Our member companies are expected to comply with a host of federal and state regulations governing dietary supplements and food in the areas of manufacturing, marketing, quality control and safety. Our supplier and manufacturer member companies also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics. Learn more about us at www.crnusa.org.

ingredients and of national brand name and private label dietary supplements, many of which are multinational and already actively selling ingredients, finished products and services globally.

Previous CRN Comments – Written, June, 2015

CRN respectfully submitted comments to the chairs of the electronic Working Group (eWG) regarding a series of ten questions, related specifically to the development of a NRV-NCD for Omega 3 (DHA/EPA). We remain committed to this process and our response to Question 4 remains relevant and has not been dismissed.

Justification of NRV-NCD Do you agree that DHA and EPA intake is sufficiently important for public health, and that all information reviewed so far justifies the establishment of an NRV-NCD for food labeling purposes? If you disagree, please justify your answer supported by scientific references.	CRN and CRN Members agree that the intake of DHA and EPA is sufficiently important for public health, and that all information reviewed so far does justify the establishment of an NRV-NCD for food labeling purposes. Further, several robust and adequately controlled "health care cost analyses" have reported that intake of DHA and EPA can lead to demonstrable public health and personal health benefits, and the reduction of significant hospitalization events. Shanahan C.J & deLorimier, R. (2014) From Science to Finance-A Tool for Deriving Economic Implications from the Results of Dietary Supplement Clinical Studies. *Jrnl. Diet. Suppl.* DOI:10.3109/19390211.2014.952866.

Previous CRN Comments – Written, August, 2015

After the Codex Alimentarius Commission (CAC) meeting in Geneva, CRN and CRN Members submitted a response to the second consultation and again applauded the scientifically-relevant process and conclusion by the chairs of the electronic Working Group. The CRN statement in support of the conclusion by the chairs of the electronic Working group is below.

"CRN is wholly in agreement with the text of the Second Consultation Document on an NRV-NCD for EPA+DHA and supports its submission for discussion at the 37th session (November 2015) of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU).

New Information; Omega-3 Acid Ethyl Esters and Post-Myocardial Infarction

A prospective multicenter, double-blind, placebo-controlled clinical trial (RCT) funded by the National institutes of Health was conducted as the OMEGA-REMODEL (Omega-3 Acid Ethyl Esters on Left Ventricular Remodeling After Acute Myocardial Infarction) trial to evaluate the hypothesis that 4 g/day of omega-3 fatty acids for 6 months post-acute myocardial infarction would provide cardia remodeling benefits, as determined by the primary study endpoint, change in left ventricular systolic volume index and secondary endpoints of change in noninfarct myocardial fibrosis, left ventricular ejection volume and infarct size (Heydari, et al., 2016[2]). The results published indicate that patients randomly assigned to the Omega-3 fatty acids treatment group had a significantly reduced left ventricular systolic volume index (-5.8%, P=0.17) and noninfarct myocardial fibrosis (-5.6%, P=0.026) in comparison to the placebo control. Further, patients treated with Omega-3 fatty acids also had a reduction in serum biomarkers of systemic and vascular inflammation and myocardial fibrosis. There were no adverse effects associate with the 4 g/day dose. This recent study provides important context to the importance of omega-3 fatty acids and a marker for cardiovascular disease.

[2] Heydari B, Abdullah S, Pottala JV, Shah R, Abbasi S, Mandry D, Francis SA, Lumish H, Ghoshhajra BB, Hoffmann U, Appelbaum E, Feng JH, Blankstein R, Steigner M, McConnell JP, Harris W, Antman EM, Jerosch-Herold M, Kwong RY. (2016).Effect of Omega-3 Acid Ethyl Esters on Left Ventricular Remodeling After Acute Myocardial Infarction: The OMEGA-REMODEL Randomized Clinical Trial. Circulation;134(5):378-91. doi: 10.1161/CIRCULATIONAHA.115.019949.

Conclusion

Nothing has been proposed in the scientific literature and/or amongst national regulatory bodies that in any way changes the conclusion of CRN and CRN Members, as echoed by the chairs of the electronic Working Group. In fact the current recommendations set by the European Food Safety Authority (EFSA) identify a 250 mg intake of EPA and DHA per day for the general adult population with a maximum tolerated dose of 5 g per day. CRN and CRN Members are in agreement with EFSA on their analysis, conclusion and recommendation!

Q10	**Proposed NRV-NCD value** If you replied affirmatively to question 9, what Reference Value amount for EPA and DHA would you propose, expecting the mentioned health benefits? Please justify your answer.	CRN and CRN Members support the establishment of a single internationally harmonized NRV-NCD for EPA and DHA combined for the general population for labeling purposes in an amount between 250-500 mg/day.

Should the eWG have further questions that CRN and CRN Members could address, please do not hesitate contacting me at your earliest convenience. CRN and CRN Members await a review of subsequent draft consultation papers.

Respectfully submitted,

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