



Council for Responsible Nutrition

1828 L Street, NW, Suite 510 • Washington, DC 20036-5114
(202) 204-7700 • fax (202) 204-7701 • www.crnusa.org

Proposal for New Work
Codex Standard for Marine Oils
Comments from the Council for Responsible Nutrition
February 4, 2011

The Council for Responsible Nutrition (CRN)

The Council for Responsible Nutrition (CRN), founded in 1973 and based in Washington, D.C., is the leading trade association representing dietary supplement manufacturers and ingredient suppliers. CRN companies produce a large portion of the 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 and drug store and discount chains. These products also include those marketed through natural food stores and mainstream direct selling companies. In addition to complying with a host of federal and state regulations governing dietary supplements in the areas of manufacturing, marketing, quality control and safety, our 75+ manufacturer and supplier members also agree to adhere to additional voluntary guidelines as well as CRN's Code of Ethics. Learn more about us at www.crnusa.org.

The Council for Responsible Nutrition (CRN) is an international non-governmental organization (NGO) officially recognized by the Codex Alimentarius for more than a decade. CRN represents the interests of national and international companies involved in all parts of the dietary supplement products and ingredient industries. CRN staff and representatives commonly participate in several Codex meetings each year, with emphasis on the CAC, CCNFSDU, CCGP, CCFA and CCFL. CRN frequently submits written comments on several scientific and technical issues, including nutrient risk assessment, nutrient reference values, health claims, and proper uses of precaution.

CRN comments on the Codex standard for marine oils: Proposal of New Work

CRN is an active supporter of the development of meaningful domestic and international standards that establish benchmarks for identity and quality. CRN supports standards that facilitate consumer access to safe and efficacious products, but is careful to avoid standards that result in unintended consequences such as hindering the global distribution of dietary supplements or stifling scientific and technological developments. CRN's support of meaningful standards is evidenced by the CRN Omega-3 Voluntary Monograph, which establishes meaningful quality parameters for omega-3 products. Such standards help to ensure that quality products reach consumers. The CRN Omega-3 Voluntary Monograph was developed by a CRN working group in response to concerns about the quality of some omega-3 EPA and DHA products on the market. A number of manufacturers of fish oils requested that CRN form a working group of companies that wished to establish a monograph prescribing analytical methods and standards of quality. The working group was established, and in 2002 published a quality monograph¹ which is widely recognized as an industry standard and demonstrates self-regulation. In 2006, the working group expanded its activities further and established itself as an independent entity, now known as the Global Organization for EPA/DHA Omega-3 (GOED). CRN members have identified several critical points that should be considered by the Codex Committee on Fats and Oils (CCFO) to help guide the decision whether to adopt the Proposal for New Work that has been submitted by the Swiss delegation. First and foremost, a standard for marine oils should set meaningful parameters for identity and quality that do not create regulatory barriers to existing international trade. The scope of the standard has the potential to impact the omega-3 industry in a variety of ways. A very concise standard has limited utility as an identity standard and may serve to commoditize specialty oils with unique features. It also may not be flexible enough to account for all oils that are currently available or oils derived from new sources. Special consideration should be given to ensure the standard is flexible enough to account for future innovations to the marine oil market, such as the utilization of new marine species and molecular delivery systems (currently available as ethyl esters, natural triglycerides, re-constituted di- and triglycerides, and phospholipids). Furthermore, when considering the

¹ CRN Omega-3 Voluntary Monograph 2006. <http://www.crnusa.org/pdfs/O3FINALMONOGRAPHdoc.pdf>

scope of a marine oils standard, non-marine sources of n-3 LCPUFA such as plant and vegetable oils, including algal oil, should not be covered.

CRN members have unanswered questions about the technical feasibility of developing a standard that is flexible enough to account for all variation in fatty acid composition for marine oils, which can be uniquely impacted by species, season, climate, harvest conditions, and diet. For example, there is a significant degree of overlap and variability in the fatty acid composition of different species that is the result of uncontrollable natural forces. Furthermore, the fatty acid composition of engineered products is company-specific. This means that using fatty acid profile as a method of identification cannot be a basis for a Codex standard unless the fatty acid profile for each product in trade is in an official register. In addition, if a Codex standard covers engineered oils, the question arises whether this standard will be limited to engineered oils that are already on the market. CRN is aware that Codex standards can be revised and updated, however it can take many years to get an existing standard modified, which may serve as an obstacle to innovation and free trade. On a final note, the degree of scientific complexity and feasibility of developing this standard should be considered in the context of the relative volume of the individual marine oils that are distributed globally.

Due to the unique nature of marine oil raw material and processing, a marine oils standard would be incomplete without specifications on quality parameters such as limits for environmental contaminants and markers of oxidation. Developing a standard that includes specifications on quality parameters would require collaboration with other Codex committees and will utilize significant Codex committee time and resources. CRN currently supports the quality parameters set forth by existing voluntary monographs, such as the CRN Voluntary Monograph and the GOED Voluntary Monograph². CRN opines that it is important that a Codex standard for marine oils is based on existing industry standards. In addition, quality parameters such as markers of oxidation can have a wide range based on the source of the oil, therefore, quality parameters may need to be independently set for each source of oil.

² GOED Voluntary Monograph. <http://www.goedomega3.com/quality-standards.html>

Conclusion

As a matter of principle, CRN is supportive of the development of global standards that facilitate access to safe and efficacious dietary supplements. These standards must not have the unintended consequence of serving as a barrier to international trade or obstacle to future innovation. If the Marine Oils Standard Proposal for New Work is adopted by the CCFO, CRN will be attentive of the standard development process to ensure the technical issues highlighted above are closely considered.

A handwritten signature in black ink, appearing to read "D. MacKay", with a checkmark-like flourish at the end.

In Health,

Douglas MacKay, ND

Vice President of Scientific and Regulatory Affairs

Council for Responsible Nutrition