



June 8, 2011

Lisa Brines
USDA - AMS - National Organic Program
Agricultural Marketing Specialist
1400 Independence Ave SW
Room 2646 South Building
Washington, DC 20250-0268

Re: DHA Algal Oil and ARA Single-Cell Oil Petitions

Dear Ms. Brines,

Attached please find a short summary of relevant references to the scientific literature and regulatory recognitions regarding the referenced Petitions. The references are provided solely to update and refresh the existing record. We wanted to be sure these were timely submitted in order that they may be made available to the technical review team. We look forward to addressing the merits of the Petitions at the National Organic Standards Board meeting in November 2011.

Please do not hesitate to contact me if you require any additional information or have any questions.

Best Regards,

A handwritten signature in blue ink that reads "Susan Cheney". The signature is fluid and cursive, with the first name "Susan" and last name "Cheney" clearly legible.

Susan Cheney
Director Regulatory Affairs
Martek Biosciences Corporation

ARA Single-Cell Oil

Evidence supporting the essentiality of dietary ARA for neural growth, development and function throughout life continues to amass.

The most recent support for the essentiality of ARA in the diet of infants comes from the Food Agriculture Organization (FAO) expert panel final report on fats and fatty acids. As originally noted, interim FAO conclusions, published early in 2010, ranked the level and strength of evidence in support of 0.4% of total fatty acids as ARA (0.2-0.3% of energy) in the diets of infants 0-6 months as “convincing”, the highest rank assigned to evidence evaluated by FAO. FAO’s recently released *final* report goes a step further recognizing the essentiality of ARA for infants, as follows, ARA “is not essential for a healthy adult whose habitual diet provides LA > 2.5%E. For infants 0-6 months ARA should be supplied in the diet within the range of 0.2-0.3%E based on human milk composition as a criterion.” [Pg. 17]

FAO goes on to note that while ARA may not be essential in the diet of healthy adults, ARA is essential for optimal neural function throughout life, specifically, that:

“There can be little doubt about the essentiality of DHA and AA for the brain. The rise in brain disorders is the most disturbing feature of the changing panorama of disease and disorder. There is a need to address the potential role of the food system as the root cause of globalization of mental ill health.” [pg. 136]

“The conclusions outlined here emphasize the need for more research in defining the requirement of the adult brain for a continuous supply of AA and DHA from the plasma for optimal neural functioning.” [Pg. 137]

The role of ARA in child health beyond neural development and function is evident from a recent study of over 23,000 Japanese school children and prevalence of the allergic disorders eczema and/or rhinoconjunctivitis (Miyake et al., 2011). Children ages 6-15 were studied via parent administered food frequency questionnaires. Dietary intake data indicate that children in the highest quintile of ARA intake had a near 20% reduced risk ($P < .0008$) of eczema (adjusted OR 0.81, CI 0.69-0.95) and a 14% reduced risk ($P < .03$) of rhinoconjunctivitis (adjusted OR 0.86, CI 0.74-0.997). Dietary DHA and EPA had no effect but both alpha-linolenic acid (18:3 n-3) and linolenic acid (18:2 n-6) were independently associated with an *increased* prevalence of eczema. These results suggest that ARA may be unique among the n-6 fatty acids with an ability to reduce the prevalence of allergic skin disorders in childhood. Similarly, prenatal exposure to increasing levels of ARA from maternal circulation has been found to be protective against eczema during the first 12 months of life (Notenboom et al., 2011). A recent animal study with Martek’s ARA and DHA has found similar results suggesting that the combination of these nutrients may directly or indirectly, via biologically active metabolites, represent “therapeutic compounds for allergen-induced dermatitis” (Weise et al., 2011).

ARA Single-Cell Oil

References:

FAO, 2010. Fats and Fatty Acids in Human Nutrition. FAO Food and Nutrition Paper 91. ISSN 0254-4725. (Final Report)

Interim Summary of Conclusions and Recommendations on Total Fat and Fatty Acids, 2010 from the Joint FAO/WHO Expert Consultation on Fats and Fatty Acids in Human Nutrition, November 10-14, 2008. WHO HQ, Geneva. (Interim Report)

Miyake Y, et al. 2011. Polyunsaturated fatty acid intake and prevalence of eczema and rhinoconjunctivitis in Japanese children: The Ryukyus Child Health Study. BMC Public Health 2011, 11:358.

Notenboom ML, et al. 2011. Maternal fatty acid status in pregnancy and childhood atopic manifestations: KOALA Birth Cohort Study. Clin Exper Allergy 41:407-416.

Weise C, et al. 2011. Dietary docosahexaenoic acid in combination with arachidonic acid ameliorates allergen-induced dermatitis in mice. *Pedi Allergy Immunology*, ahead of print. DOI:10.1111/j.1399-3038.2010.01133.x