

Standards Management Officer
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Date
March 28, 2012

Your reference
Comment to FSANZ
P293

Contact person
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Dear All

Re: Submission – Proposal P293 Nutrition, Health & Related Claims

Table 1: Revised draft Standard 1.2.7

Submitter name: DSM, Nutritional Lipids division	
1. Does the revised drafting accurately capture the regulatory intent as provided in Attachment B? Please consider the clarity of drafting, any enforceability issues and the level of “user-friendliness”.	
Schedule	Comment
Schedule 2 – EPA and DHA and heart health	<p>DSM applauds the pre-approval of over 100 general level health claims in the current draft standard to include the relationship between the omega-3 fatty acids, docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA), and heart health.</p> <p>DSM is concerned, however, that inconsistent conditions of use proposed for the DHA+EPA general level health claim (GLHC) and nutrient content claim (NCC) may limit the usefulness of these claims and thus the ability to educate consumers regarding the health benefits of these fatty acids. <i>Specifically, conditions of use for the</i></p>

	<p><i>proposed DHA+EPA GLHC are 10 mg lower (50 mg/serving) than that specified for a “good source” NCC (60 mg/serving). It is quite possible that a “good source” NCC will resonate with some consumers while others will find the GLHC more meaningful making the simultaneous use of these claims logical. It is respectfully requested that FSANZ consider increasing the GLHC condition of use to 60 mg for ease of use by manufacturers and increased usefulness to consumers. It is likely that failure to unite the conditions of use for the DHA+EPA “good source” NCC and the heart health GLHC may result in consumer confusion. Precedent for consistency between NCCs and GLHCs has been set by the European Commission where conditions of use for the DHA+EPA and cardiovascular health claim and “good source” NCC are aligned.</i></p> <p>With regard to other DHA+EPA GLHC conditions of use, DSM would also like to request two additional modifications.</p> <p>First, while it is critically important to disallow “omega-3” as a stand-alone descriptor, and thereby avoid perpetuation of consumer confusion by implying that all omega-3s have the same efficacy, <i>please consider allowance of the term “long-chain omega-3” in combination with DHA and/or DHA+EPA, e.g. DHA long-chain omega-3.</i> This terminology will help consumers to distinguish among fatty acids with varying efficacy. (Similar, this more definitive terminology should also be applied to omega-3 NCC including alpha-linolenic acid, i.e., “ALA short-chain omega-3”)</p> <p><i>Second, that the conditions of use for DHA+EPA and heart health be revised to recognize that the minimum amount can be satisfied either by DHA alone or by EPA+DHA. Positive EFSA opinions have been rendered for DHA alone or EPA+DHA and maintenance of normal triglycerides.^{1,2}</i></p>
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¹ EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to EPA, DHA, DPA and maintenance of normal...maintenance of normal (fasting) blood concentrations of triglycerides (ID 517)... pursuant to Article 13(1) of Regulation (EC) No 1924/2006 on request from the European Commission. EFSA Journal 2009; 7(9):1263. [26 pp.]. doi:10.2903/j.efsa.2009.1263. Available online: www.efsa.europa.eu

² EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion the substantiation of a health claim related to docosahexaenoic acid (DHA) and maintenance of normal (fasting) blood concentrations of triglycerides (ID 533, 691, 3150)...



	<p>Recent evidence also indicates equal or greater reduction in various markers of atherosclerosis, including blood pressure, by DHA alone when compared to DHA+EPA.³</p> <p>Finally, DSM looks forward to the opportunity to comment on FSANZ proposals for translation of various EU health claims, currently pending authorization, to pre-approved GLHCs. <i>DSM respectfully requests, however, that FSANZ prioritize the pre-approval of claims for DHA and maintenance of brain function and normal vision in the general population.² In addition, DSM also respectfully requests that FSANZ consider currently authorized EU claims for maternal DHA intake and support of infant brain and eye development as pre-approved GLHC.⁴</i> Given the authorized status of these claims, adoption in the current Standard would be appropriate.</p>
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Sincerely

Rodney JH Gray
Vice President Global Regulatory Affairs
DSM Nutritional Lipids

maintenance of normal brain function (ID 565, 626, 631, 689, 690, 704, 742, 3148, 3151), maintenance of normal vision (ID 627, 632, 743, 3149)... pursuant to Article 13(3) of Regulation (EC) No 1924/2006. EFSA Journal 2010;8(10):1734. [27 pp.].
doi:10.2903/j.efsa.2010.1734. Available online: www.efsa.europa.eu/efsajournal.htm

³ Kelley and Adkins, 2012. Chronic and degenerative diseases: Similarities and differences between the effects of EPA and DHA on markers of atherosclerosis in human subjects. Proc Nutr Soc Feb 28 1-10. Doi:10.1017/S002966511200080.

⁴ Commission Regulation (EU) No 440/2011 of 6 May 2011 on the authorisation and refusal of authorisation of certain health claims made on foods and referring to children's development and health. L119/4 7.5.2011.