



Submission to Food Standards Australia New Zealand

from

The Omega-3 Centre

Proposal P293
Nutrition, Health & Related Claims
Consultation Paper for Review 17 February 2012

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PREFACE

The Omega-3 Centre is established as a centre of evidence-based information on omega-3 fatty acids (omega-3s) for Australia and New Zealand. Founded in 2006, The Omega-3 Centre (O3C) is a well-recognised and credible source of information on health issues related to long chain omega-3s. The O3C is supported by a group of committed organisations and individuals working together to improve the health status of the community by promoting optimal intakes of long chain omega-3s.

There are 10 full-members of the O3C representing major food manufacturers, seafood industry, omega-3 ingredient suppliers, and research and development organisations:

- Clover Corporation / Nu-Mega Ingredients
- Ocean Nutrition Canada
- DSM Nutritional Lipids
- Nutricia Australia
- Simplot Australia
- New Zealand King Salmon
- Fisheries Research & Development Corporation
- CSIRO Food Futures Flagship
- GC Rieber Oils AS
- NuSeed Global
- Massey University, NZ

The O3C liaises with scientific experts in a wide range of areas to help ensure the information we disseminate is accurate and based on current knowledge.

The O3C scientific committee includes:

- Professor Andrew Sinclair, Deakin University, Australia – Scientific Adviser, Research
- Dr Laurence Eyres – Scientific Adviser, Lipid Chemistry, New Zealand
- Dr David Roberts– Scientific Adviser, Policy & Regulatory Affairs
- Dr Peter Nichols, CSIRO Food Futures Flagship, Australia – Scientific Adviser, Seafood
- Ms Wendy Morgan – Scientific Adviser, Nutrition

The O3C welcomes the opportunity to respond to the Consultation Paper (dated 17 February 2012) for Proposal P293, Nutrition, Health & Related Claims.

Introduction

The O3C supports the guiding principles for the regulation of health claims, in particular, provision of a system that is flexible yet enforceable, protects public health and safety, provides adequate information about food and is cost effective.

The various health benefits of consuming long chain omega-3s are well-documented and indicate their importance in heart health and in supporting optimal visual and cognitive development. However, current intake levels in the Australian population are well below optimal intakes as recommended by the NHMRC and NHFA.

The development of a new Standard that supports meaningful and evidence-based health claims will provide industry with an effective way of communicating health messages that will benefit public health. For instance, raising awareness of the benefits of consuming more long chain omega-3 containing foods will potentially contribute to an increase in intake of these beneficial long chain fatty acids towards optimal levels.

In this submission, the O3C will address issues raised in the Consultation Paper with respect to their relevance and impact on omega-3 communications in the current marketplace and provision of adequate information about food to assist consumers in making informed and healthier choices.

The O3C will comment on the structure and regulatory clarity of draft Standard 1.2.7 as discussed in Part I of the consultation paper only.

1. Revision of the draft Standard

The O3C supports the redrafting of the Standard 1.2.7 in relation to improved clarity and user-friendliness.

2. Regulation of Health Claims

The O3C supports a health claim regulation, where lower level health claims (previously called General Level Health Claims) do not require regulatory pre-approval and that other less onerous options should be considered such as a co-regulatory system or Code of Practice. However, if the current proposed pre-approval system does go ahead, the O3C have outlined a number of concerns that would need to be addressed.

2.1 Incomplete health claim list on Omega-3s.

The O3C supports the inclusion of the pre-approved health claim: “EPA and DHA contributes to heart health” given the strong level of scientific evidence for the diet-disease relationship between these long chain omega-3 fatty acids and cardiovascular health^{1 2}.

We also support the requirement for a minimum content of 50mg DHA and EPA per serving of food as this reflects 10% of the 500mg daily intake target recommended by the National Heart Foundation of Australia as achieving a heart health benefit.

¹ NHMRC. Nutrient Reference Values for Australia and New Zealand. Canberra: Commonwealth of Australia, 2006

² NHFA. Position statement Fish, fish oils, n-3 polyunsaturated fatty acids and cardiovascular health. National Heart Foundation of Australia, 2008.
http://www.heartfoundation.org.au/document/NHF/HW_FS_FishOils_PS_FINAL.pdf

However, the O3C has noted that the current health claim list is incomplete and does not include a health claim in relation to DHA and its role in the normal development of the brain and eyes. There is a substantial body of evidence on the importance of adequate amounts of DHA in supporting optimal visual and cognitive development³.

A claim in this area of health is consistent with international practice:

- 'Biological Roles Claims', Health Canada and CFIA include: "**DHA, an omega-3 fatty acid, supports the normal development of the brain, eyes and nerves**"⁴.
- In December 2011, the European Union Standing Committee on the Food Chain and Animal Health (SCOFAH) voted to adopt a Commission Regulation authorizing a list of Article 13 claims that includes several omega-3 claims⁵. Specifically, the claims and conditions of use for the claims are:
 - **DHA contributes to the maintenance of normal brain function**
Conditions of use of claim: The claim may be used only for food which contains at least 40 mg of DHA per 100 g and per 100 kcal. In order to bear the claim, information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 250 mg of DHA.
 - **DHA contributes to the maintenance of normal vision**
Conditions of use of claim: The claim may be used only for food which contains at least 40 mg of DHA per 100 g and per 100 kcal. In order to bear the claim, information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 250 mg of DHA.

The O3C notes that FSANZ did include a pre-approved nutrient function statement related to DHA and the normal development of the brain, eyes and nerves in the P293 Draft Assessment Report (*Attachment 10 Substantiated High Level and General Level Health Claims, Appendix 1 Pre-Approved Nutrient Function*

³ Koletzko, B et al The roles of long-chain polyunsaturated fatty acids in pregnancy, lactation and infancy: review of current knowledge and consensus recommendations J.Perinat.Med.36(2008) 5-14

⁴ Diet Related Health Claims, CFIA, Canadian Food Inspection Agency, Guide to Food Labelling and Advertising, 2007 (www.inspection.gc.ca)

⁵European Food Safety Association

Statements for Recognised Nutrients, Table 2: Pre-approved statements for nutrients other than vitamins and minerals, page 42) released on 7 December 2005.

Subsequently, this pre-approved claim was removed by FSANZ from the pre-approved list of GLHC on the basis of “*there are no criteria for qualifying claims about DHA in the Code on which to base a GLHC*”.

Given the evidence-base for such a claim, the O3C recommends this issue is reviewed and ***FSANZ should adapt the DHA health claims approved in the European Union immediately*** into Draft Standard 1.2.7. The O3C stands ready to assist FSANZ in the development of qualifying criteria for DHA claims and can provide guidance in assembling the evidence.

The O3C recommends the qualifying criteria for a DHA claim should be consistent with the DHA and EPA criteria proposed in Draft Standard 1.2.7. Please refer to the table in Attachment 1, which lists the proposed omega-3 claims for Draft Standard 1.2.7.

For the DHA and EPA claims in the Draft Standard 1.2.7, the minimum levels are per serving of food, where as the European Union minimum levels are per 100g and per 100kcal of food.

The O3C suggests the minimum level of DHA for a claim to the effect that “DHA contributes to the maintenance of normal brain function and normal vision” should be ***per serving*** of food to be consistent with the reasoning for the minimum level established for the “EPA and DHA contributes to heart health” claim, which is as follows.

Claim	Type of claim	Min levels	Qualifying criteria	NPSC	Based on...
EPA and DHA contributes to heart health	Health claim	50mg DHA and EPA per serving of food	In order to bear the claim, information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 500 mg of DHA.	No	This reflects 10% of the 500mg daily intake target recommended by the National Heart Foundation of Australia as achieving a heart health benefit

The DHA claim proposed by the European Union is 40mg per 100g and 100kcal – ***not per serving of food.***

Claim	Type of claim	Min levels	Qualifying criteria	NPSC	Based on...
DHA contributes to the maintenance of normal brain function and normal vision	Health claim	40 mg of DHA per 100 g and per 100 kcal	In order to bear the claim, information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 250 mg of DHA.	No	EU Standing Committee on the Food Chain and Animal Health (SCOFAH) < Dec 2011

This issue demonstrates the importance of a flexible approach in the development of a health claim Standard that does not stifle, but supports industry innovation and meaningful evidence-based communication.

2.2 Nutrient Profiling Score Criterion not supported

The O3C does not support the requirement that foods making health claims need to meet a nutrient profiling scoring criterion (NPSC).

The current criteria for making an omega-3 nutrition content claim in the existing *Standard 1.2.8* is sufficient criteria for an omega-3 health claim thus making a NPSC irrelevant for omega-3 fatty acid health claims.

Current criteria is as follows:

Claim	Type of claim	Min levels	Qualifying criteria	NPSC	Based on...
Source or good source omega-3s	Nutrient content claim	Source: 200 mg ALA or 30mg EPA&DHA per serving; Good source: 60mg EPA&DHA per serving	A claim must not be made in relation to the omega-3 fatty acid content of a food, other than fish or fish products that have no added saturated fatty acids, unless the – (a) total of saturated fatty acids and trans fatty acids is no more than 28% of the total fatty acid content of the food; or (b) food contains no more than 5 g of saturated fatty acids and trans fatty acids per 100 g of the food.	No	Current Std 1.2.8

Appropriate nutrient criteria already exists for an omega-3 claim, therefore it would be a burden to industry for their products to comply with a NPSC and the criteria for making an omega-3 claim when there is no evidence to support this is necessary for foods making an omega-3 claim.

In further support of this, few foods are significant sources of long chain omega-3s. In the context of very low intakes of these nutrients in the diets of most children and adults in Australia and NZ we recommend that using a NPSC system would limit relevant and useful information for all consumers.

2.3 The 'Pre-approved health claim process' needs to allow industry to communicate new science effectively and quickly

The O3C supports the inclusion of pre-approved food-health relationships in draft Standard 1.2.7 and the opportunity for industry to prepare their own wording of the health claim. The O3C supports the FSANZ plan to adapt acceptable health claims approved by the EU for inclusion as food-health relationships in *Standard 1.2.7*. The O3C strongly recommends the 'screening' and 'public comment' to be undertaken quickly to enable industry the opportunity to communicate relevant and useful health claims to consumers.

As previously mentioned the O3C recommends ***FSANZ adapt the health claims for 'DHA' approved in the European Union immediately*** into Draft Standard 1.2.7. The O3C stands ready to assist FSANZ in the development of qualifying criteria for DHA claims and can provide guidance in assembling the evidence. It would be appropriate for the minimum levels of DHA to be 'per serving of food' so it is consistent with other omega-3 criteria proposed in Draft Standard 1.2.7. Please refer to the table in Attachment 1, which lists the proposed omega-3 claims for Standard 1.2.7.

The O3C supports a pre-approval process for 'new claims' that is confidential and provides industry exclusivity and market advantage.

Conclusion

The O3C supports the guiding principles for the regulation of health claims, in particular, provision of a system that is flexible yet enforceable, protects public health and safety, provides adequate information about food and is cost effective.

The O3C supports a health claim regulation, where lower level health claims (previously called General Level Health Claims) do not require regulatory pre-approval and that other less onerous options should be considered such as a co-regulatory system or Code of Practice.

The various health benefits of consuming long chain omega-3s are well-documented and indicate their importance in heart health and in supporting visual and cognitive development. However, current intake levels in the Australian population are well below optimal intakes as recommended by the NHMRC and NHFA.

It is therefore essential that the health claims encompass relevant and meaningful omega-3 claims to raise awareness of the health benefits of omega-3s and lead to increased intakes of these beneficial fatty acids in the Australian diet.

As a key health stakeholder, the O3C welcomes further opportunities for consultation and provision of advice on long chain omega-3s in relation to P293, Nutrition, Health & Related Claims.

Attachment 1: Proposed Omega-3 Claims for Draft Standard 1.2.7

Claim	Type of claim	Min levels	Qualifying criteria	NPSC	Based on
Source or good source omega-3s	Nutrient content claim	Source: 200 mg ALA or 30mg EPA&DHA per serving; Good source: 60mg EPA&DHA per serving	A claim must not be made in relation to the omega-3 fatty acid content of a food, other than fish or fish products that have no added saturated fatty acids, unless the – (a) total of saturated fatty acids and trans fatty acids is no more than 28% of the total fatty acid content of the food; or (b) food contains no more than 5 g of saturated fatty acids and trans fatty acids per 100 g of the food.	No	Current Std 1.2.8
EPA and DHA contributes to heart health	Health claim	50mg DHA and EPA per serving of food	In order to bear the claim, information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 500 mg of DHA.	No	This reflects 10% of the 500mg daily intake target recommended by the National Heart Foundation of Australia as achieving a heart health benefit
DHA contributes to the maintenance of normal brain function	Health claim	40 mg of DHA per 100 g and per 100 kcal	In order to bear the claim, information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 250 mg of DHA.	No	EU Standing Committee on the Food Chain and Animal Health (SCOFAH)< Dec 2011
DHA contributes to the maintenance of normal vision	Health claim	40 mg of DHA per 100 g and per 100 kcal	In order to bear the claim, information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 250 mg of DHA.	No	EU Standing Committee on the Food Chain and Animal Health (SCOFAH)< Dec 2011