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Health claims policy

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Health claims policy

Abstract

Abstract presented at The 2nd Omega Workshop, 30 September 2002, Adelaide, Australia.

Keywords

claims, health, policy

Disciplines

Education | Social and Behavioral Sciences

Publication Details

Yeatman, H. (2002). Health claims policy. Food Australia: The Omega Workshop: Report and presentations, 54 (11), 511.

been established for the general population. In February 2001, the US Food and Drug Administration issued a Qualified Health Claim for omega-3 fatty acids and CHD: "...The scientific evidence about whether omega-3 fatty acids may reduce the risk of CHD is suggestive, but not conclusive... It is not known what effect omega-3 fatty acids may or may not have on risk of CHD in the general population."

The workshop's panel of twelve experts in omega-3 fatty acids and/or clinical trials concluded that in order to achieve a health claim, a primary prevention trial was needed which would:

- 1) provide more data directly linking omega-3 fatty acids and CHD risk reduction,
- 2) be carried out in patients at high-risk of, but without diagnosed, CHD,
- 3) include clinical endpoints and well-recognised surrogates of CHD risk, and
- 4) demonstrate efficacy of a dose of omega-3 fatty acids that is within reach of dietary recommendations.

If an international trial is initiated through an NIH grant, Australia would have an opportunity to participate.

Regulation of LCPUFA: sources and claims

Janine Lewis; Food Standards Australia New Zealand, Canberra

FSANZ recently approved specifications for food ingredients that contain high proportions of LCPUFA, including oils derived from sources such as fungal or marine algae that are considered to be novel. These ingredients are in the form of oils or powder.

Criteria for omega claims were introduced as Standard 1.2.8 of Volume 2 of the *Food Standards Code* in December 2000 to expand the range of permitted claims for polyunsaturated fats in response to the increased use of 'omega' in food labelling. Positive and negative criteria were set on the basis of amounts of particular fatty acids in foods, since no official reference daily intakes were available.

For omega-3 claims, all foods, except fish with added saturated fat, must contain less than 28% total fatty acids in saturated and trans form; or no more than 5 g saturated and trans fatty acids/100g food. Also, for 'source' claims, the food must contain at least: 200 mg ALA/serve; or 30 mg EPA + DHA/serve; for 'good source' claims at least 60 mg EPA + DHA/serve.

For omega-6; -9 claims, all foods must contain no more than 28% of total fatty acids in saturated and trans form and no more than 40% total fatty acid as the claimed fatty acid.

Fatty acid declarations in the nutrition information panel (NIP) are arranged in nested order according to specificity. For example, an omega-3 claim would require the declaration of fat and types of fatty acids to four levels: fat; polyunsaturated (as well as saturated, monounsaturated and trans); omega-3, and individual fatty acids, eg EPA and DHA.

Health claims policy

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The review of the regulation of health claims, and of nutrition and related claims, has been underway in Australia and New Zealand for several years. With the creation of the new food regulatory arrangements in Australia, the Ministerial Council requested the development of policy guidelines to inform the development of regulations in this area. The policy guidelines are currently being developed by the Food Regulation Standing Committee, via a working group chaired by the Food Policy Unit of the Commonwealth Department of Health and Ageing. The Policy Guidelines will be considered by the Ministerial Council in November 2002, and will incorporate principles agreed in May 2002 and a 'watchdog' to monitor the use of health and related claims.

Regulatory update – European position

Peter Weber; Roche Vitamins Ltd, Switzerland

In Europe, natural food-grade fish oils as well as natural vegetable oils obtained by conventional oil processing are considered components of natural food and can be added to food products without any registration as long as the food standards for fats, oils and related products are met. Food supplements containing natural marine/vegetable oils are individually regulated in the different member states of the European Community (EC). Products derived from microorganisms (eg algae) as well as concentrated oils are regarded as Novel Food within the EC and have to be approved under the harmonised EC Novel Food Regulation (EEC No. 258/97). Omega-3/6 oils for use in infant formulae are regulated in separate Directives (EEC 91/321, EC 96/4). For products containing ethyl esters, different regulations apply in the individual member states of the EC. Regarding health claims related issues, the EC currently provides little guidance, this again is individually regulated by the different countries of the EC. However, the EC is intending to harmonise food law on health claims and a draft paper has been proposed.

Intakes and food sources of omega-6 and omega-3 PUFA

**Barbara Meyer, Peter Howe, Janine Lewis, Greg Milligan, Neil Mann and Andrew Sinclair; *University of Wollongong, Wollongong*

Estimates of the ω_6 and ω_3 PUFA intakes and food sources in the Australian diet were assessed using food records from 10 851 adults in the 1995 Australian National Nutrition Survey. Existing fatty acid composition data on 1690 foods taken from the Supplement to NUTTAB95 was used together with newly validated data on 150 foods to estimate the fatty acid content and the food sources.

Average daily intakes of linoleic, arachidonic, total ω_6 PUFAs, α -linolenic (LNA), EPA, DPA, DHA, very