

“Plant stanol esters have been shown to lower/reduce blood cholesterol. Blood cholesterol lowering may reduce the risk of coronary heart disease”.

More information from FIEN news service on this follows:

Plant Stanol Esters and Blood Cholesterol - Food Labeling Health Claim - The Panel on Dietetic Products, Nutrition and Allergies of the European Food Safety Authority has released an opinion which finds that " ... there is evidence that the risk of CHD can be decreased by cholesterol-lowering therapy including dietary intervention strategies ... products to which plant stanol esters are added should be consumed only by people who need and want to lower their blood cholesterol and that patients on cholesterol-lowering medication should only consume the product under medical supervision ... the following wording reflects the available scientific evidence: 'Plant stanol esters have been shown to lower/reduce blood cholesterol. Blood cholesterol lowering may reduce the risk of coronary heart disease' ..."

Document Title: The title of the October 31, 2008 Opinion of the EFSA Panel on Dietetic Products, Nutrition and Allergies, which was adopted on October 2, 2008 is "Plant stanol esters and blood cholesterol - Scientific substantiation of a health claim related to plant stanol esters and lower/reduced blood cholesterol and reduced risk of (coronary) heart disease pursuant to Article 14 of Regulation (EC) No 1924/2006[1] - Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies"

Organization: European Food Safety Authority

Summary: The text of the Summary of the October 31, 2008 EFSA Opinion follows

Plant stanol esters and blood cholesterol - Scientific substantiation of a health claim related to plant stanol esters and lower/reduced blood cholesterol and reduced risk of (coronary) heart disease pursuant to Article 14 of Regulation (EC) No 1924/2006[1] - Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies

Question number: EFSA-Q-2008-118

Adopted date: 02/10/2008

Summary

Following an application from McNeil Nutritionals, submitted pursuant to Article 14 of Regulation (EC) No 1924/2006 via the Competent Authority of United Kingdom, the Panel on Dietetic Products, Nutrition and Allergies was asked to deliver an opinion on the scientific substantiation of a health claim related to “Plant stanol esters and lowering/reducing blood cholesterol and reducing the risk of coronary heart disease”.

The scope of the application was proposed to fall under a health claim referring to reduction of a disease risk.

In the context of this application, the term “plant stanol ester” refers to a blend of the plant stanols sitostanol and campestanol, which are obtained from the saturation of plant sterols from food grade plant oils, mainly soybean oil, and esterified with fatty acids from food grade low erucic acid rapeseed oil. The Panel considered that the plant stanol esters for which the health claim is proposed have been sufficiently characterised.

Elevated low-density lipoprotein (LDL) blood cholesterol is one recognised risk factor for coronary heart disease (CHD). CHD is an important cause of mortality and morbidity. Lowering LDL-cholesterol by dietary intervention has been shown to reduce the risk of coronary heart disease. The Panel considers that the claimed effect of lowering LDL-cholesterol is beneficial to human health.

The applicant provided an unpublished meta-analysis comprising 30 randomised, double-blind placebo controlled trials, with generally healthy, normo- and moderately hypercholesterolaemic male and female subjects.

On the basis of the data presented, a clinically significant LDL-cholesterol lowering effect of about 10% can be achieved by a daily intake of plant stanol esters equivalent to 2 g of plant stanols in an appropriate food (e.g. fat-based foods and low-fat foods such as yoghurt), preferably with meals. The size of the cholesterol lowering effect may differ in other food matrices. The Panel concludes that a cause-effect relationship has been established between the intake of plant stanol esters and lowering of LDL-cholesterol, in a dose-dependent manner.

With respect to the association of LDL-cholesterol lowering with reduction in the risk of CHD, the Panel considers that there is evidence that the risk of CHD can be decreased by cholesterol-lowering therapy including dietary intervention strategies. However, there are no studies demonstrating that plant stanol esters have an impact on population-based CHD morbidity and mortality rates.

The Panel considers that products to which plant stanol esters are added should be consumed only by people who need and want to lower their blood cholesterol and that patients on cholesterol-lowering medication should only consume the product under medical supervision.

The Panel considers that the following wording reflects the available scientific evidence: “Plant stanol esters have been shown to lower/reduce blood cholesterol. Blood cholesterol lowering may reduce the risk of coronary heart disease”.

[1] For citation purposes: Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies on a request from McNeil Nutritionals Ltd. related to the scientific substantiation of a health claim on plant stanol esters and lower/reduced blood cholesterol and reduced risk of (coronary) heart disease. The EFSA Journal (2008) 852, 1-13.

Source: October 31, 2008 EFSA Opinion, which was adopted on October 2, 2008 by the EFSA Panel on Dietetic Products, Nutrition and Allergies

Web site: The opinion is posted at

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902157684.htm

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