

Position statement

Phytosterol/stanol enriched foods 2007

Updated December 2009

This position statement was developed to help the public and health professionals better understand the role of phytosterol/stanol enriched foods for lowering low-density lipoprotein cholesterol (LDL-C) and reducing cardiovascular disease risk.

Key findings

Cardiovascular disease (CVD) is a leading cause of death and a major cause of disability in Australia.¹ Recent data reports that nearly 47,000 Australians died from CVD in 2007.¹

The cause of most CVD is atherosclerosis. LDL-C is the major atherogenic component of plasma and high-density lipoprotein cholesterol (HDL-C) is the anti-atherogenic component. Epidemiological data have shown a continuous linear relationship between LDL-C levels and CHD events.^{2,3} Studies indicate that incorporating phytosterol/stanols into the diet may be an effective method of lowering total and LDL-C levels.

The Heart Foundation conducted an update of the literature around phytosterol/stanols and an update of their 2003 position statement⁴ to:

- examine the cholesterol-lowering effect of phytosterol/stanol enriched foods
- determine recommendations for phytosterol/stanol enriched foods
- comment on the safety/efficacy of consuming phytosterol/stanol enriched foods.





Recommendations

The Heart Foundation makes the following recommendations for phytosterol intake to reduce the LDL-C level of adult Australians and so reduce the current level of CVD.

In general, children (other than those with familial hypercholesterolaemia) and lactating or pregnant women do not need phytosterol enriched foods because it is not appropriate to reduce their cholesterol absorption.

Adult Australians with high absolute risk of CVD

Adult Australians with high absolute risk of CVD benefit from the cholesterol-lowering effect of consuming naturally occurring phytosterols in plant foods and phytosterol enriched foods. Therefore, the Heart Foundation recommends they do the following.

1. Consume 2–3 g of phytosterols per day from margarine, breakfast cereal, reduced fat yoghurt or reduced fat milk enriched with phytosterols. As Australian regulations allow a minimum of 0.8 g and a maximum of 1.0 g phytosterols per serve of food, this is two or three serves per day of these fortified foods.
2. Consume phytosterols within a healthy balanced diet low in saturated and trans fat and high in oily fish, wholegrains, fruits and vegetables. See the Heart Foundation's *Healthy eating and drinking tips* at www.heartfoundation.org.au for more information.

In particular, choose at least one daily serve of fruit or vegetable high in beta-carotene such as:

- carrots, pumpkin, broccoli, spinach and squash
- apricots, mangoes and rockmelon.

Health professionals

1. Encourage adult Australians with evidence of CVD, familial hypercholesterolaemia or diabetes to include phytosterol enriched foods as part of a healthy balanced diet as described above.
2. Advise adult Australians on statin therapy about the benefits of consuming phytosterol enriched foods.
3. Advise adult Australians with sitosterolaemia to restrict their intake of phytosterols.
4. Supervise compliance with cholesterol-lowering medicines.

All Australians

1. Discuss healthy eating and concerns about nutrition with an accredited practising dietitian or a doctor.
2. Visit the Heart Foundation's website www.heartfoundation.org.au or ring the Health Information Service on 1300 36 27 87 (local call cost) for further information about healthy eating.

Background information

Phytosterols (or plant sterols) are an essential component of cell membranes and are produced by plants but not the human body. Stanols are saturated sterols; they have no double bond in the sterol ring, and are much less abundant. Phytosterols and stanols are similar in structure to cholesterol, but in comparison to cholesterol, phytosterols and stanols are not absorbed, or are minimally absorbed.

Daily phytosterol consumption is estimated to be between 160 to 400 mg in various populations.⁵

The cholesterol-lowering effect of phytosterol/stanol enriched foods has been well documented.^{6,7} Systematic reviews studying the efficacy of phytosterols have shown that phytosterol/stanol enriched foods can significantly lower LDL cholesterol.^{6,8}

Summary of evidence

The below findings are based on the scientific literature discussed in the Heart Foundation's *Summary of evidence. Phytosterol/stanol enriched foods*.

Evidence	Level of evidence
Phytosterols lower LDL-C in people with normocholesterolaemia, hypercholesterolaemia and diabetes.	I
For people with increased risk of CVD, consuming phytosterol/stanol enriched foods provides an additional option for risk reduction through lowering the level of cholesterol.	II
A daily intake of approximately 2 g of phytosterol/stanol from enriched margarine reduces LDL-C levels by approximately 10%, but has little effect on HDL-C or triglycerides.	I
A daily intake of approximately 2.5 g of phytosterols from enriched breakfast cereal, reduced fat yoghurt, reduced fat milk or bread reduces LDL-C levels by approximately 5 to 15%.	II
Consuming phytosterol/stanol enriched foods at levels higher than 2–3 g per day provides no additional benefits to lowering LDL-C.	I
Daily consumption frequency does not influence the cholesterol-lowering efficacy of phytosterol/stanols.	II
Phytosterol/stanol enriched foods have an additive effect in lowering LDL-C when combined with statins.	II
There are no reported adverse effects from daily consumption of phytosterol/stanol enriched foods, although long-term safety information is not available.	II
When consuming phytosterol/stanol enriched foods, blood carotenoids are reduced. An additional serving of high-carotenoid fruit and vegetables is effective in maintaining blood carotenoid concentrations.	II
People with the rare inherited metabolic disease homozygous sitosterolaemia have high blood phytosterol levels and premature atherosclerosis. Restricted intake of phytosterols is recommended for these individuals.	II

Future research

There is no consistent evidence that would lead to safety concerns associated with the short-term consumption of phytosterols and stanols, although long-term safety studies have not been performed.

Long-term cholesterol-lowering studies with phytosterol intervention would be needed to demonstrate actual prevention of CVD, but are unlikely to occur.

Further work is needed to evaluate the effects of phytosterol-rich plant foods as a natural source of phytosterols that may lower cholesterol. The role of phytosterols in modifying the development of atherosclerotic plaque warrants further research.

Data will continue to be monitored by the Heart Foundation, especially with respect to potential adverse effects. Reduction in carotenoids and possibly tocopherols is one such area.

Rating of the evidence

Evidence is graded according to the NHMRC guidelines.⁹

Levels of evidence for clinical interventions

Level of evidence	Study design
I	Evidence obtained from a systematic review of all relevant randomised controlled trials.
II	Evidence obtained from at least one properly designed randomised controlled trial.
III-1	Evidence obtained from well-designed pseudo-randomised controlled trials (alternate allocation or some other method).
III-2	Evidence obtained from comparative studies with concurrent controls and allocation not randomised, cohort studies, case-control studies, or interrupted time series with a control group.
III-3	Evidence obtained from comparative studies with historical control, two or more single-arm studies, or interrupted time series without a parallel control group.
IV	Evidence obtained from case series, either post-test or pre-test and post-test

References

1. Australian Bureau of Statistics. Causes of Death 2007 (3303.0). March 2009.
2. Zhang X, Patel A, Horibe H et al. Cholesterol, coronary heart disease, and stroke in the Asia Pacific region. *Int J Epidemiol* 2003; Aug; 32: 563–72.
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4. Heart Foundation. Plant sterols and stanols. A position statement from the National Heart Foundation of Australia's Nutrition and Metabolism Advisory Committee, Melbourne: National Heart Foundation of Australia; 2003.
5. Ostlund R Jr. Phytosterols in human nutrition. *Annu Rev Nutr* 2002; 22, 533–549.
6. Law M. Plant sterol and stanol margarines and health. *BMJ* 2000; Mar 25; 320: 861–4.
7. Plat J, Kerckhoffs D, Mensink R. Therapeutic potential of plant sterols and stanols. *Curr Opin Lipidol* 2000; 11: 571–76.
8. Normen L, Holmes D, Frohlich J. Plant sterols and their role in combined use with statins for lipid lowering. *Curr Opin Investig Drugs* 2005; Mar 6: 307–16.
9. National Health and Medical Research Council. A guide to the development, implementation and evaluation of clinical practice guidelines. Canberra: National Health and Medical Research Council; 1999.



For heart health information
1300 36 27 87
www.heartfoundation.org.au

Visit www.heartfoundation.org.au/Professional_Information/Lifestyle_Risk/Nutrition for:

- Q&As on plant sterol enriched foods
- Summary of evidence. Phytosterol/stanol enriched foods.

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