Nutritional Risk Assessment – LDL cholesterol-lowering effects of tall oil plant sterols in a new food

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Background

Plant sterols are added to foods to lower serum LDL cholesterol (LDL) levels. Although a large body of literature concludes that plant sterols lower LDL, the reduction can be affected by the food matrix, solubility and method of incorporation into foods.

To date, plant sterols have been permitted in margarines, milk, bread and cereal in Australia and New Zealand.

Recently, FSANZ received new policy guidance that "consistency with stated purpose" should be included in future assessments of novel foods.

Subsequently an Application seeking permission to add tall oil derived phytosterol esters to a new food product, reduced fat cheeses, was received.

Objective

To assess whether tall oil derived phytosterol esters delivered in reduced fat cheese would lower LDL.

Design

FSANZ identified only a few studies that examined the addition of plant sterol mixtures specifically to cheese, and so the assessment was broadened to include additions to all dairy products.

A systematic literature review and meta-analysis was done as outlined in Table 1 and Figure 1.

Approach to assessment and sources of data

- Study results were reported in a variety of ways
- The difference in change in lipids between the intervention and control group was used when this was reported and calculated when it was not (Higgins & Green, 2009).
- When the change in lipids within the intervention or control arms was not reported in parallel studies a correlation of 0.8 was used to calculate the standard deviation of difference within arms.
- Where a study contained multiple intervention arms and a single control group, intervention groups were averaged to address the correlation in effects between multiple intervention groups (Higgins & Green, 2009).
- Studies reporting in mg/dL were converted to mmol/L by dividing by 38.67.
- Analysis was done with StatsDirect software (StatsDirect Ltd).
- No dose-response assessment was done because previous reviews indicate little dose response in the 1-3g daily range (Demonty, 2007).

Table 1: Inclusion and exclusion criteria

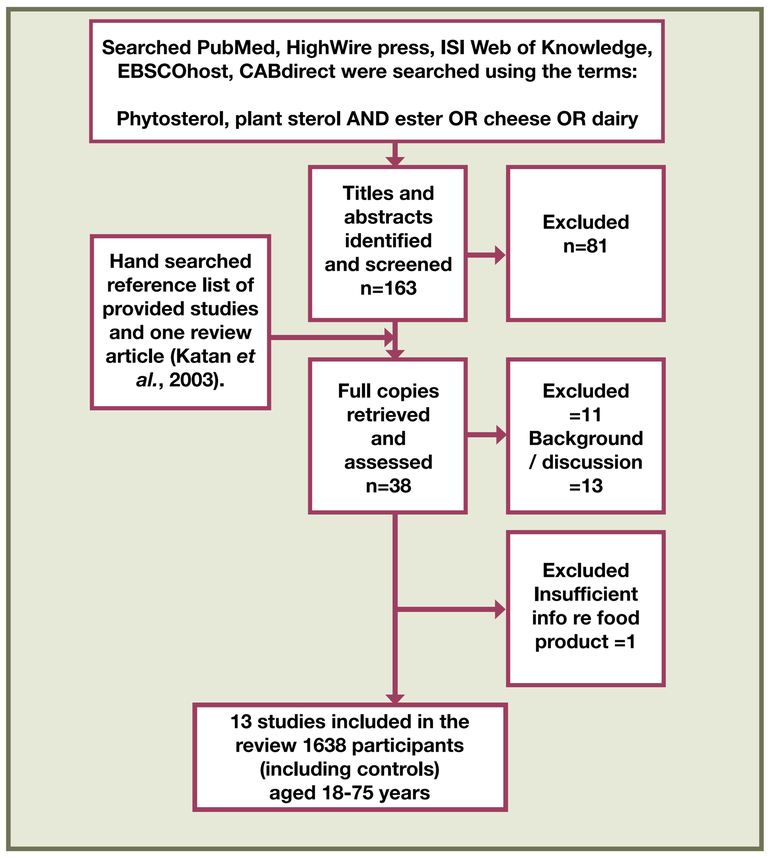
Table 1a: Inclusion criteria

Human study
Examined effects of tall-oil derived or vegetable oil derived phytosterols and their esters on LDL
Randomised control trial (parallel or cross-over design)
Minimum intervention duration 3 weeks
Minimum participant age of 18 years
Subjects with normal or elevated cholesterol levels
Dairy based foods containing protein
Administered a control dietor a placebo vehicle

Table 1b: Exclusion criteria

No measure of LDL
Studies including oil based spreads or butter
Phytosterols delivered as a supplement
Co-interventions
Subjects with diseases (eg Kidney disease)
Incomplete results or unable to be calculated
Did not use commercial mixture of plant sterol

Figure 1: QUOROM diagram for literature search process

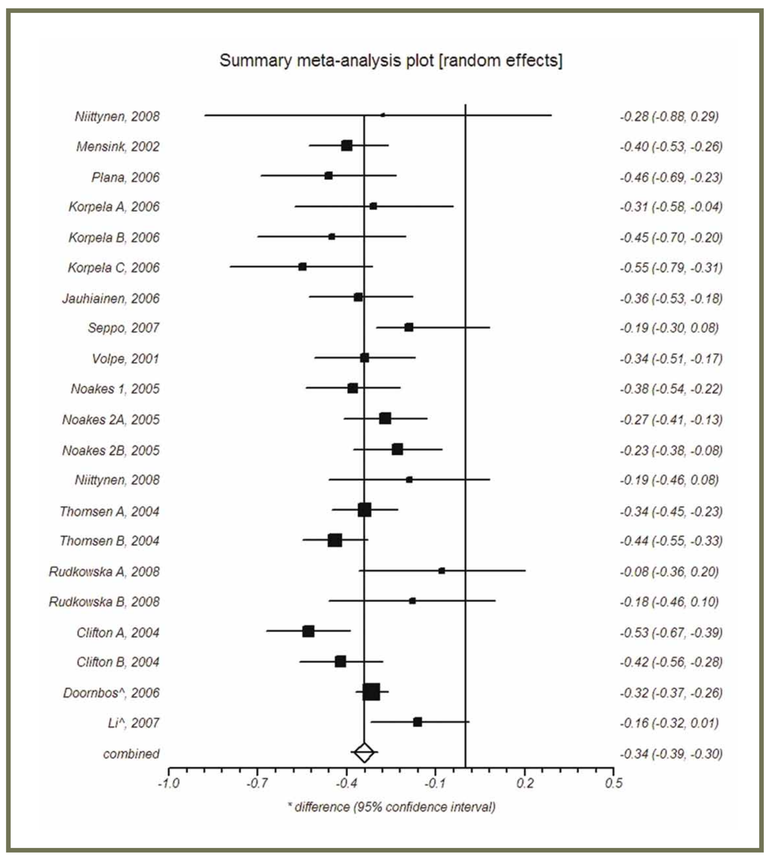


Results

Overview of data

The 13 identified studies are shown in Figure 2. Plant sterols were delivered in yoghurt, milk, fermented milk and cheese.

Figure 2: Forest plot of change in LDL cholesterol (mean in mmol/L)



1,2 indicates different studies from the same author

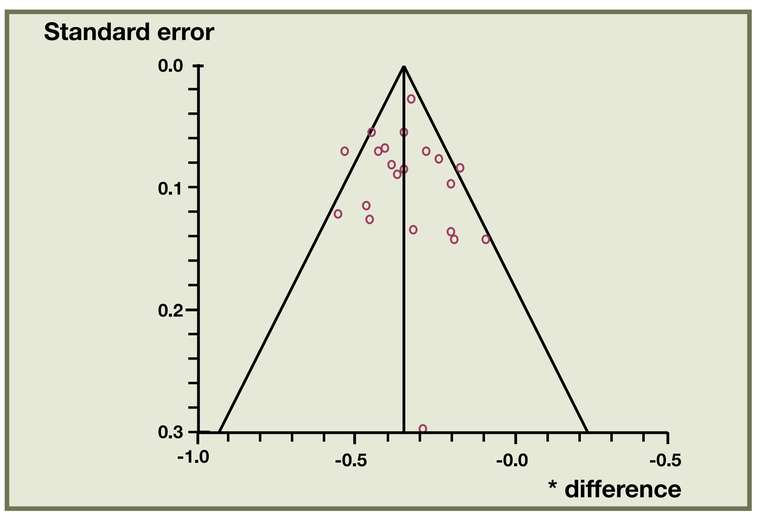
A, B, C, D indicates different trial arms in the same study

- The mean plant sterol intake was 1.9 g/day (range 1-3.2 g/day).
- The mean baseline LDL ranged between 3.67 and 4.83 mmol/L.

Effects of plant sterols in cheese and dairy products on LDL cholesterol

- All studies reported a reduction in LDL, ranging from -0.16 to -0.53 mmol/L.
- The average absolute decrease in LDL was 0.34 mmol/L (95% CI:-0.39 to -0.30).
- I^2 was 40.9% (95 CI: 0 – 63.8%) which indicates moderate inconsistency among the study results (Higgins & Green, 2009)[1].
- Figure 3 shows no evidence of bias in study result reporting.

Figure 3: Bias assessment plot



Conclusion

- When added to reduced fat cheese and other reduced fat dairy products, plant sterols lower LDL.
- The LDL reductions in the reduced fat cheese studies show the same range of LDL effect as when other reduced fat dairy foods are used.
- FSANZ considers that tall-oil derived plant sterol mixtures in reduced fat cheese products can lower LDL in adults

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Footnotes

1. I^2 is a statistic for quantifying inconsistency across studies to assess the impact of heterogeneity on the meta-analysis. v

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