Newsletter September 2012

(If you want to comment my letter, please use my other email ravnskov@tele2.se)

Fraudulent advertising for food containing plant sterols.

For many years Unilever has marketed its margarine Becel pro-activ (Flora pro-activ) and certain yoghurt products with the argument that they lower cholesterol. The cholesterol-lowering effect is due to the addition of plant sterols extracted from soya beans and Finnish timber using extraction petrol. The effect is that less normal cholesterol and more plant sterols are taken up by the gut resulting in higher levels of plant sterols and lower levels of human cholesterol in the blood

Now to the problem. Several studies have shown that an increased level of plant sterols is associated with an increased formation of atherosclerosis, heart disease and premature death. In the following I shall mention the most important of these studies. I have also included the web address for these studies.

High levels of plant sterols in the blood characterize a rare inborn disease named sitosterolemia, and patients with this disease develop xanthomas already in childhood. Xanthomas are benign tumours situated in the skin consisting of cholesterol and are seen in many patients with extremely high cholesterol, so-called familial hypercholesterolemia. In sitosterolemia these tumours also contain many plant sterols (reference 1).

Several researchers have documented that patients with sitosterolemia become atherosclerotic in early childhood and may die from a coronary already as teenagers (references 2-5).

There are of course good reasons why animals and human beings are using the cholesterol molecule instead of plant sterols to build cell walls and to produce bile, various hormones, vitamin D and other useful substances. It is therefore no surprise that exchanging our own cholesterol with plant sterols are harmful as has been demonstrated in experiments on rats fed large amounts of plant sterols. Not only was this diet harmful to their cells; it shortened their life as well (reference 6).

In an analysis of one of the first statin experiments researchers led by Finnish scientist Tatu Miettinen found that 25 percent of the patients had an elevated level of plant sterol in their blood. These patients did not benefit from statin treatment; on the contrary their risk of heart disease increased (reference 7).

In a review from 2003 (reference 8) all trials using food rich in plant sterol were analysed. The review was sponsored by Unilever, the main author's research was also paid by Unilever; two of the other authors have patents on margarine containing plant sterols, and one of them had shares in the Finnish company Raisio, which produces margarine containing plant sterol. The authors concluded that plant sterols are harmless referring to animal experiment as evidence ignoring the rat study mentioned above (reference 6). They dismissed the studies reporting early atherosclerosis and cardiovascular death in sitosterolemia with the following argument: "This risk is believed to be largely hypothetical, and any increase due to the small increase in plasma plant sterols may be more than offset by the decrease in plasma LDL".

In their review the authors claimed that a study has shown that patients with sitosterolemia can eat plant sterols without risk. That study was included in a list of 33 similar experiments (reference 9) with the aim to measure the effect of plant sterol intake on the plasma lipids in human beings. With one exception all of them had a duration of less than nine weeks, almost all of them were performed for 3-4 weeks only. One wonder why it has been necessary to do 33 experiments (most of them paid by Unilever) with the only purpose to show that plant sterols lower cholesterol. Why has nobody performed a five-year controlled experiment to study the effect on cardiovascular events?

The authors of reference 8 also ignored Miettinens previous study (reference 7) showing that statin treatment increases the risk of heart disease in people with raised plasma levels of plant sterols, although Miettinen was a co-author of the review.

In some of their advertisements Unilever uses a report from European Food Safety Authority published in 2008 (reference 10) as support, but the authors of that report have not considered possible adverse effects either. They conclude that the plant sterols lower cholesterol, but also that "there are no human intervention studies demonstrating that plant stanols

reduce the risk of coronary heart disease."

In this connection it is relevant to mention that many studies have shown that the effect of the statins do not depend on the very lowering of cholesterol because the benefit is the same whether cholesterol is lowered a little or very much. This fact explains why the patients in the 4S trial, whose plant sterol levels were high, did not benefit from statin treatment, although their cholesterol was lowered just as much or more than the other participants'. Therefore the argument that plant sterols lower cholesterol is misleading, because most people think that cholesterol lowering is synonymous with a lowering of cardiovascular risk.

A few weeks ago I sent this report to the Swedish Consumer Ombudsman with the purpose to stop the promoting of food enriched with plant sterols. You are most welcome to send it to a similar governmental authority in your own country

Here follow the references to the scientific studies mentioned above (click on the authors name to read the full paper) together with a selection of quotations from these papers:

1. <u>Bhattacharyya and Connor 1974</u>. Sitosterolemia and Xanthomatosis. A newly described lipid storage disease in two sister.

"Although the usual diet may contain 150-250 mg of plant sterols, chiefly f8-sitosterol, only trace amounts of these sterols have heretofore been found in human or animal blood and tissues. We now report elevated plant sterol levels in the blood and tissues of two sisters with extensive tendon xanthomas but normal plasma cholesterol levels. Besides. P-sitosterolemia and xanthomatosis, no other physical, mental, or biochemical abnormalities were detected..... We suggest that increased absorption of P-sitosterol must be considered as one cause of this disease. The reason for the extensive xanthomatosis in these two patients remains unknown. Perhaps in some way plant sterols initiated the development of xanthomas with otherwise normal plasma cholesterol levels. Clinical atherosclerosis has not yet occurred."

2. <u>Beaty et al 1986</u>. Genetic Analysis of Plasma Sitosterol, Apoprotein B, and Lipoproteins in a Large Amish Pedigree with Sitosterolemia

"We previously reported the finding of phytosterolemia, xanthomatosis, and hyperapobetalipoproteinemia (hyperapoB) in five siblings in a large Amish pedigree ascertained through a 13-year-old boy who died suddenly from advanced coronary atherosclerosis.....The plasma levels of total and low density lipoprotein (LDL) sterol remain normal or moderately elevated in sitosterolemia [1-9]. Each of the 16 reported cases developed tendon xanthomas before the age of 10 years, and atherosclerosis of the coronary arteries, aorta, and aortic valve (producing aortic stenosis) occurred as early as the second decade of life [1-9]."

3. <u>Salen et al. 1985</u>: Lethal atherosclerosis associated with abnormal plasma and tissue sterol composition in sitosterolemia with xanthomatosis.

"These results indicate that cholesterol, plant sterols, and 5a-stanols are deposited prematurely and are associated with accelerated atherosclerosis in subjects with sitosterolemia with xanthomatosis."

4. <u>Assman G. et al. 2006</u>: Plasma sitosterol elevations are associated with an increased incidence of coronary events in men: Results of a nested case-control analysis of the Prospective Cardiovascular Münster (PROCAM) study. "Conclusions: Elevations in sitosterol concentrations and the sitosterol/cholesterol ratio appear to be associated with an increased occurrence of major coronary events in men at high global risk of coronary heart disease."

5. Weingärtner et al. 2009. Controversial role of plant sterol esters in the management of hypercholesterolaemia "Summary points: Currently there are no data available indicating that functional foods supplemented with plant sterol esters reduce cardiovascular events. Findings in patients with the hereditary disease of sitosterolaemia, data from epidemiological studies, as well as recently published in vitro and in vivo data suggest that plant sterols potentially induce negative cardiovascular effects. Prospective clinical studies testing relevant clinical endpoints are needed, before a diet supplementation with plant sterol esters can be recommended."

6. <u>Walisundera et al. 2000</u>. Vegetable Oils High in Phytosterols Make Erythrocytes Less Deformable and Shorten the Life Span of Stroke-Prone Spontaneously Hypertensive Rats.

"This study suggests that the high concentration of phytosterols in CA and the addition of phytosterols to other fats make the cell membrane more rigid, which might be a factor contributing to the shortened life span of SHRSP rats."

7. <u>Miettinen TA et al</u>. 1998. Baseline serum cholestanol as predictor of recurrent coronary events in subgroup of Scandinavian simvastatin survival study.

"The risk of recurrence of major coronary events increased 2.2-fold (P<0.01) by multiple logistic regression analysis

between the lowest and highest quarter of cholestanol....Conclusions: Measurement of serum cholestanol concentration revealed a subgroup of patients with coronary heart disease in whom coronary events were not reduced by simvastatin treatment." (No, it increased; my comment)

8. Katan MB et al. 2003. Efficacy and Safety of Plant Stanols and Sterols in the Management of Blood Cholesterol Levels

<u>9</u>. <u>Stalenhoef AFH et al. 2001</u>. Effect of plant sterol-enriched margarine on plasma lipids and sterols in subjects heterozygous for phytosterolaemia.

10. <u>European Food Safety Authority 2008.</u> SCIENTIFIC OPINION. Plant stanol esters and blood cholesterol "There are no human intervention studies demonstrating that plant stanols reduce the risk of coronary heart disease....The product may not be nutritionally appropriate for pregnant and breastfeeding women and children under the age of five years. Patients on cholesterol lowering medication should only consume products with added plant stanol esters under medical supervision."

Uffe Ravnskov, MD, PhD, independent investigator Spokesman of <u>THINCS</u>, The International Network of Cholesterol Skeptics Magle Stora Kyrkogata 9, 22350 Lund, Sweden tel +46 46145022 or +46-702580416 www.ravnskov.nu/uffe My books <u>My newsletters</u>

This letter has been sent to you because you have previously shown interest in the many contradictions of the diet-cholesterol-heart hypothesis and/or the work of our group THINCS, The International Network of Cholesterol Skeptics (<u>www.thincs.org</u>). If you do not wish to be on the mailing list, please contact me and I shall delete your name