

foodwatch e.v. · brunnenstraße 181 · d-10119 berlin

European Commission
Directorate General for Health
and Food Safety
Attn: Vytenis Andriukaitis
B - 1049 Brussels
Belgium

In advance by E-Mail:
CAB-ANDRIUKAITIS-WEBPAGE@ec.europa.eu

Berlin, 31 August 2015

Application for revocation of the permission to market Becel pro.activ (Unilever) and other "yellow fat spreads with added phytosterol esters" as novel food or novel food ingredient under the Regulation (EC) No 258/97 of the European Parliament and of the Council

Dear Mr Andriukaitis, Commissioner for Health and Food Safety,

On 24 July 2000, the European Commission authorised the placing on the market of food with added phytosterol esters as a novel food (Decision 2000/500/EC). We hereby apply for this authorisation to be revoked.

Article 3, para 1 of the Regulation concerning novel foods and novel food ingredients ("Novel Food Regulation") states:

*"Foods and food ingredients falling within the scope of this Regulation **must not** present a danger for the consumer."* (Emphasis added by foodwatch)

Since the authorisation in 2000, numerous studies calling in question the safety of these products have been published. As a result, findings exist now which had not been available at the time the authorisation was granted. The risk assessment resulting from these findings contradicts the Novel Food Regulation, as the regulation demands that any danger for the consumers' health must be ruled out.

Risks resulting from food with added phytosterol esters

Among others, the following studies indicating potential health risks resulting from the consumption of food containing phytosterol esters have been published since 2000:

- Rajaratnam et al. Independent association of serum squalene and noncholesterol sterols with coronary artery disease in postmenopausal women. *J Am Coll Cardiol.* 2000 Apr; 35(5):1185-91.
- Thiery et al. Abstract 4099: Elevated Campesterol Serum Levels - a Significant Predictor of Incident Myocardial Infarction: Results of the Population-based MONICA/KORA Follow-up Study 1994 to 2005 *Circulation*, Oct 2006; 114: II_884.
- Assmann et al. 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. *Nutr Metab Cardiovasc Dis.* 2006 Jan;16(1):13-21. Epub 2005 Jul 28.

- Weingärtner et al. Vascular effects of diet supplementation with plant sterols. J Am Coll Cardiol. 2008 Apr 22; 51(16):1553-61.
- Helske et al. Accumulation of cholesterol precursors and plant sterols in human stenotic aortic valves. J Lipid Res. 2008 Jul; 49(7):1511-8. Epub 2008 Apr 8.
- Teupser et al. Genetic regulation of serum phytosterol levels and risk of coronary artery disease. Circ Cardiovasc Genet. 2010 Aug; 3(4):331-9.
- Kelly et al. Effects of long term plant sterol and -stanol consumption on the retinal vasculature: a randomized controlled trial in statin users. Atherosclerosis. 2011 Jan; 214(1):225-30.

As early as in 2008, the German Federal Institute for Risk Assessment (BfR) assessed the health risk resulting from food with added plant sterols and concluded:

"Overall, studies emphasise that healthy people without elevated cholesterol levels should expressly avoid the consumption of food with added phytosterols." (BfR opinion no. 042/2008 of 3 September 2008)

In 2011, the BfR furthermore assessed a current study from the Netherlands (Kelly et al. 2011) and concluded:

"The findings of the study indicate that intake of plant sterols may entail cardiovascular risks for healthy persons who consume foods containing plant sterols in relatively large quantities and over a long period of time." (BfR opinion 006/2012 of 1 December 2011)

The BfR furthermore stated:

"The BfR has already pointed out in earlier opinions that foods to which plant sterols or stanols are added are largely consumed by persons who do not have increased cholesterol levels as well as by children." (BfR opinion 006/2012 of 1 December 2011)

In cases of doubt, the "precautionary principle" established by European food law (Reg 178/2002) places the EU Commission under the obligation to decide in favour of the consumers' health.

For reasons of precautionary health protection, we hereby apply for the revocation of the authorisation 2000/500/EC and for a prohibition of placing on the market "yellow fat spreads with added phytosterol esters" like Becel pro.activ (Unilever).

We kindly ask for your response until 1 October 2015.

Yours sincerely



Oliver Huizinga
Campaigner