HEALTH CLAIMS ON PECTINS APPROVED BY EFSA

Scientific Opinion on the substantiation of health claims related to pectins and reduction of post-prandial glycaemic responses (ID 786) and maintenance of normal blood cholesterol concentrations (ID 818) pursuant to Article 13(1) of Regulation (EC) No 1924/2006.

Summary

EFSA approved the following health claims:
“Consumption of pectins contributes to the reduction of the blood glucose rise after meals”. 
“Consumption of pectins contributes to the maintenance of normal blood cholesterol levels”.

Reduction of post-prandial glycaemic responses

The claimed effect is “reduces the postprandial levels of glucose”. The target population is assumed to be individuals willing to reduce their post-prandial glycaemic responses. The Panel considers that reduction of post-prandial glycaemic responses (as long as post-prandial insulinaemic responses are not disproportionally increased) may be a beneficial physiological effect.

In weighing the evidence, the Panel took into account the consistency of a post-prandial blood glucose-lowering effect of pectins consumed in foods or meals across the studies considered, and that the mechanism by which pectins could exert the claimed effect is well known.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has been established between the consumption of pectins and a reduction of post-prandial glycaemic responses.

The Panel considers that, in order to bear the claim, foods should provide at least 10 g of pectins per meal. The target population is adults willing to reduce their post-prandial glycaemic responses.

Maintenance of normal blood cholesterol concentrations

The claimed effect is “cholesterol maintenance”. The target population is assumed to be the general population. The Panel considers that maintenance of normal blood cholesterol concentrations is a beneficial physiological effect.

In weighing the evidence, the Panel took into account the consistency of the total and LDL-cholesterol lowering effect of pectins across the studies considered, and that the mechanism by which pectins could exert the claimed effect is well known.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has been established between the consumption of pectins and maintenance of normal blood cholesterol concentrations.

The Panel considers that, in order to bear the claim, foods should provide at least 6 g per day of pectins in one or more servings. The target population is adults.
ASSESSMENT

1. Characterisation of the food/constituent

The food constituent that is the subject of the health claims is pectins. Pectins are composed of linear chains of alpha-(1,4)-galacturonic acid units with varying degrees of methylation and side chains including galacturonic and glucuronic acids. Pectins are viscous and water-soluble but unavailable for digestion in the human small intestine. Pectins are found in fruits and vegetables, and they are used as thickeners by the food industry. The Panel considers that the food constituent, pectins, which is the subject of the health claims is sufficiently characterised.

2. Relevance of the claimed effect to human health

2.1. Reduction of post-prandial glycaemic responses (ID 786)

The claimed effect is “reduces the postprandial levels of glucose”. The Panel assumes that the target population is individuals willing to reduce their post-prandial glycaemic responses. The Panel notes that the claimed effect relates to the reduction of post-prandial glycaemic responses. Postprandial glycaemia is interpreted as the elevation of blood glucose concentrations after consumption of a food and/or meal. This is a normal physiological response that varies in magnitude and duration and may be influenced by the chemical and physical nature of the food or meal consumed, as well as by individual factors (Venn and Green, 2007). The evidence provided does not establish that decreasing post-prandial glycaemic responses in subjects with normal glucose tolerance is a beneficial physiological effect. However, it may be beneficial to subjects with impaired glucose tolerance as long as post-prandial insulinaemic responses are not disproportionally increased. Impaired glucose tolerance is common in the general population of adults. The Panel considers that the reduction of post-prandial glycaemic responses (as long as post-prandial insulinaemic responses are not disproportionally increased) may be a beneficial physiological effect.

2.2. Maintenance of normal blood cholesterol concentrations (ID 818)

The claimed effect is “cholesterol maintenance”. The Panel assumes that the target population is the general population. The Panel notes that the claimed effect relates to the maintenance of normal blood cholesterol concentrations. Low-density lipoproteins (LDL) carry cholesterol from the liver to peripheral tissues, including the arteries. Elevated LDL-cholesterol, by convention >160 mg/dL (>4.14 mmol/L), may compromise the normal structure and function of the arteries. High-density lipoproteins (HDL) act as cholesterol scavengers and are involved in the reverse transport of cholesterol in the body (from peripheral tissues back to the liver). The Panel considers that maintenance of normal blood cholesterol concentrations is a beneficial physiological effect.
3. Scientific substantiation of the claimed effect

3.1. Reduction of post-prandial glycaemic responses (ID 786)

A review of 16 intervention studies in humans investigating the effects of pectins in post-prandial blood glucose responses was provided (Reiser, 1987). Four of these studies were conducted in diabetic subjects under pharmacological treatment for blood glucose control. Two studies were on the combined effects of pectins plus guar gum and one study was on guar gum alone. In four studies plasma insulin concentrations were not reported. The Panel considers that no conclusions can be drawn from these references for the substantiation of the claimed effect.

Several studies investigated the effects of pectins in various doses (between 10 and 20 g/meal) and in various types of meals (pectins incorporated in marmalade or juice or added to a glucose drink) compared to the same foods or meals without pectins (Jenkins et al., 1977, 1978; Gold et al., 1980; Sahi et al., 1985; Haber et al., 1977; Bolton et al., 1981) following a randomised cross-over design. Five of the studies showed significant reductions in postprandial blood glucose responses after consumption of pectin-containing foods or meals (Jenkins et al., 1977, 1978; Gold et al., 1980; Sahi et al., 1985; Bolton et al., 1981). In three of the studies postprandial insulin responses were significantly lower with the pectin-food or meal (Jenkins et al., 1977, 1978; Bolton et al., 1981), whereas no differences between interventions were observed in two studies (Gold et al., 1980; Sahi et al., 1985). The Panel notes that all the studies were small and included between five and ten healthy subjects.

The remaining studies were a meta-analysis of randomised controlled trials in humans and a rat study on the effects of different dietary fibres, including pectins, on blood cholesterol concentrations, a narrative review on the effects of pectins on human metabolism, a rat study on the action of various pectins on glucose uptake in intestinally perfused rats and a human intervention study on the effects of pectins combined with guar gum on post-prandial blood glucose responses. None of these references investigated the effects of pectins alone on post-prandial blood glucose responses in humans. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claimed effect. The effect of pectins (a water-soluble fibre) on the post-prandial blood glucose concentrations is partly related to a decreased rate of diffusion of available carbohydrates to the absorptive mucosal surface partially due to a delay in gastric emptying.

In weighing the evidence, the Panel took into account the consistency of a post-prandial blood glucose-lowering effect of pectins consumed in foods or meals across the studies considered, and that the mechanism by which pectins could exert the claimed effect is well known.

The Panel concludes that a cause and effect relationship has been established between the consumption of pectins and a reduction of post-prandial glycaemic responses.

3.2. Maintenance of normal blood cholesterol concentrations (ID 818)

All the studies presented in the consolidated list assessing the effects of pectins on blood cholesterol in humans have been considered in one review and one meta-analysis of randomised controlled trials (Reiser, 1987; Brown et al., 1999).

In a meta-analysis of randomised controlled intervention studies on the effects of different types of soluble fibre (including pectins) on the blood lipid profile (Brown et al., 1999), seven studies on pectins including 277 subjects (216 men) were considered (mean age 50 years, range 31-65 years). Four studies had a cross-over design (n=88) and three had a parallel design (95 and 94 subjects randomised to the pectins and control groups, respectively). Four studies were on healthy subjects, one in hypercholesterolaemic subjects, one in diabetics.
and one in subjects at high risk of coronary heart disease. The seven studies considered had total cholesterol and triglyceride concentrations as outcomes, whereas only six assessed changes in HDL-cholesterol concentrations and four in LDL-cholesterol concentrations. Initial serum total and serum LDL-cholesterol concentrations were 5.62 ± 0.7 mmol/L and 4.01 ± 0.59 mmol/L, respectively. The mean dose of pectins used in the studies was 4.7 g per day (range 2.2-9 g per day), and the average length of treatment was 34 days (range 28-42 days). Five studies used a low-fibre control, whereas in two the control was diet only. The meta-analysis showed a statistically significant effect of pectins on serum total and LDL-cholesterol concentrations at doses of 2.2 to 9 g per day. There was a significant dose-response relationship between the intake of soluble fibre (including pectins) and the total and LDL-cholesterol-lowering effect, whereas the dose-response relationship was not significant for HDL-cholesterol and triglycerides. It was estimated that one gram of pectins per day produced a change in total and LDL-cholesterol concentrations of -0.07 (95 %CI = -0.117 to -0.022) and -0.05 mmol/L (95 %CI = -0.087 to -0.022), respectively. These changes were statistically significant. No significant changes in HDL-cholesterol or triglycerides were observed in relation to pectin consumption.

In the review by Reiser (1987), 18 studies on pectins using doses of 2 to 40 g per day were included. The individual studies included 6 to 30 mostly healthy subjects. In 14 of them pectins showed a significant effect on serum total cholesterol concentrations. LDL-cholesterol concentrations were generally not assessed. In the dose-response study in 16 subjects by Palmer and Dixon (1966), doses of 2 to 10 g per day were used. Doses of 6 to 10 g per day significantly reduced serum total cholesterol concentrations by 4 to 6 %, whereas the effects of 2 to 4 g per day were statistically non significant.

Like for other water-soluble fibres, the effect of pectins on blood (LDL) cholesterol concentrations is likely to depend on its viscosity, which reduces the reabsorption of bile acids, increases the synthesis of bile acids from cholesterol and reduces circulating blood cholesterol concentrations.

In weighing the evidence, the Panel took into account the consistency of the total and LDL-cholesterol lowering effect of pectins across the studies considered, and that the mechanism by which pectins could exert the claimed effect is well known.

The Panel considers that a cause and effect relationship has been established between the consumption of pectins and maintenance of normal blood cholesterol concentrations.

4. Panel’s comments on the proposed wording

4.1. Reduction of post-prandial glycaemic responses (ID 786)

The Panel considers that the following wording reflects the scientific evidence: “Consumption of pectins contributes to the reduction of the blood glucose rise after meals”.

4.2. Maintenance of normal blood cholesterol concentrations (ID 818)

The Panel considers that the following wording reflects the scientific evidence: “Consumption of pectins contributes to the maintenance of normal blood cholesterol levels".

Source: EFSA Journal 2010;8(10):1747
5. Conditions and restrictions of use

5.1. Reduction of post-prandial glycaemic responses (ID 786)

The Panel considers that, in order to bear the claim, at least 10 g of pectins per meal should be consumed. The target population is adults willing to reduce their post-prandial glycaemic responses.

5.2. Maintenance of normal blood cholesterol concentrations (ID 818)

The Panel considers that, in order to bear the claim, at least 6 g per day of pectins should be consumed in one or more servings. The target population is adults.

CONCLUSIONS

On the basis of the data presented, the Panel concludes that:

- The food constituent, pectins, which is the subject of the health claims is sufficiently characterised

Reduction of post-prandial glycaemic responses (ID 786)

- The claimed effect is “reduces the postprandial levels of glucose”. The target population is assumed to be individuals willing to reduce their post-prandial glycaemic responses. Reduction of post-prandial glycaemic responses (as long as post-prandial insulinaemic responses are not disproportionally increased) may be a beneficial physiological effect.
- A cause and effect relationship has been established between the consumption of pectins and a reduction of post-prandial glycaemic responses.
- The following wording reflects the scientific evidence: “Consumption of pectins contributes to the reduction of the blood glucose rise after meals”.
- In order to bear the claim, at least 10 g of pectins per meal should be consumed. The target population is adults willing to reduce their post-prandial glycaemic responses.

Maintenance of normal blood cholesterol concentrations (ID 818)

- The claimed effect is “cholesterol maintenance”. The target population is assumed to be the general population. Maintenance of normal blood cholesterol concentrations is a beneficial physiological effect.
- A cause and effect relationship has been established between the consumption of pectins and maintenance of normal blood cholesterol concentrations.
- The following wording reflects the scientific evidence: “Consumption of pectins contributes to the maintenance of normal blood cholesterol levels”.
- In order to bear the claim, at least 6 g per day of pectins should be consumed in one or more servings. The target population is adults.
DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1573, EFSA-Q-2008-1605, EFSA-Q-2010-00645). The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The full list of supporting references as provided to EFSA is available on: http://www.efsa.europa.eu/panels/nda/claims/article13.htm.

REFERENCES


