

17 June 2011

Mr B. Mathioudakis
European Commission
SANCO

Dear Mr Mathioudakis,

This letter refers to the scientific opinion published by EFSA on 25 May 2011 related to "low fat and low trans spreadable fat rich in unsaturated and omega-3 fatty acids" and reduction of LDL-cholesterol concentrations pursuant to Article 14 of Regulation (EC) No 1924/2006¹ (later: Opinion).

Referring to the Article 16.6 of the Nutrition and Health Claims Regulation 1924/2006/EC² (later: Regulation), Raisio Nutrition Ltd. (later: Raisio) would like to share our concerns with regard the health claim proposed by the EFSA in its opinion.

Main concerns:

- The condition of use needs to define the g/day amount of mixed SFAs that should be replaced by cis-MUFAs and/or cis-PUFAs
- All food products bearing an art. 14 cholesterol lowering claim should state the extent of cholesterol lowering the product will provide when consumed in recommended amounts.
- A definition for "balanced and varied diet" is needed. Will the claimed cholesterol lowering effect be obtained by persons already adhering to a balanced and varied diet?
- Can art. 14 health claims be approved for diets according to the Regulation?
- Decision needed if art. 13 "maintenance of normal cholesterol levels" and art. 14 "cholesterol reduction" health claims in fact are the same as EFSA requires scientific substantiation of a cholesterol lowering

Unclear definition of the condition of use

The main objective of the Regulation is to protect the consumer from misleading health claims. Hence, the condition of use of an approved health claim must be unambiguously defined in order to prevent misinterpretations by food companies potentially leading to misleading of the consumer.

EFSA concludes in its Opinion:

"In order to bear the claim, significant amounts of mixed SFAs should be replaced by cis-MUFAs and/or cis-PUFAs in foods or diets on a gram-per-gram basis as per Annex of Regulation (EC) No 1924/2006 as amended by Regulation (EC) No 116/2010 and in accordance with the Guidance on the implementation of Regulation (EC) No



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1924/2006 of the Standing Committee on the Food Chain and Animal Health for comparative nutrition claims made on foods (section 2.2.3). The target population is subjects who want to lower their blood cholesterol."

Raisio does not find the proposed condition of use to be clear, nor precise enough to guide food companies how to correctly implement the approved health claim. It is unclear what is meant by "**significant amounts of mixed SFAs**". In order to clearly guide the food marketers the condition of use needs to define the amount of SFAs in g/day that needs to be replaced by cis-MUFAs and/or cis-PUFAs.

Based on the ambiguous condition of use proposed by EFSA it is also unclear what forms the basis for the comparison. For example as the applicant suggested: can butter or stick margarine be compared to margarine-type spreads that are rich in cis-MUFAs and/or cis-PUFAs or should the comparison be made for example within the same food category only, e.g. the margarine category? Or can any high SFA containing product be compared to a product fulfilling the provisions of the Annex of Regulation (EC) No 1924/2006 as amended by Regulation (EC) No 116/2010³?

Example of peer-review published clinical studies, where the replacement of SFAs with cis-MUFAs and/or cis-PUFAs has lead to statistically significant reductions in serum LDL cholesterol levels

The impact on serum LDL- cholesterol has e.g. been evaluated in the following two studies that compared customary daily intakes of standard vegetable-oil-based spread and butter.

In a study by Hendriks et al. 1999⁴, replacing 25 g of butter for 25 g of commercially available Flora spread reduced LDL-cholesterol by 4.0%. 25 g of butter contained about 11 g more SFA and 8 g less PUFA and 1 g less MUFA than standard spread (Table 1). A similar study was published in 2004 by Cleghorn et al. ⁵ In this cross-over study, consumption of 27 g/d of standard PUFA spread was compared to consumption of 21 g/d of butter for 3 weeks. Butter contained 8 g/d more SAFA and 8 g/d less PUFA and 2 g/d less MUFA than standard PUFA spread. Consumption of standard PUFA spread reduced LDL-cholesterol by 5.5% compared to butter.



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Table 1. The fat content and fat composition of butter and spread and the fat intake during butter and spread periods in two studies.

Hendriks et al., Eur J Clin Nutr 1999		
Daily fat-intake from study products during study periods		
	Butter (24.8 g/d)	Flora spread (24.8 g/d)
Total fat (g/d)	20.73	17.21
SAFA (g/d)	14.86	3.79
MUFA (g/d)	3.74	4.98
PUFA (g/d)	0.37	8.18
Results		
	End of butter period	End of Flora spread period
Total cholesterol (mmol/L)	5.27	5.16*
LDL Cholesterol (mmol/L)	3.15	3.05**

* reduction compared to butter 2.6 % (p<0.05)

** reduction compared to butter 4.0 % (p<0.05)

From Table 4

Cleghorn et al., Eur J Clin Nutr 2003		
Daily fat-intake from study products during study periods		
	Butter (21 g/d)	PUFA spread (27 g/d)
Total fat (g/d)	17.22	18.9
SAFA (g/d)	12.57	4.53
MUFA (g/d)	4.13	6.05
PUFA (g/d)	0.52	8.13
Results		
	End of butter period	End of PUFA spread period
Total cholesterol (mmol/L)	6.09	5.81*
LDL Cholesterol (mmol/L)	3.98	3.76**

* reduction compared to butter 4.6 % (p<0.01)

** reduction compared to butter 5.5 % (p<0.05)

From Table 6

The results from these studies imply that replacement of at least 8-11 g of SFAs per daily portion of a food with cis-MUFAs and/or cis-PUFAs on a gram per gram basis is needed to obtain a statistically significant reduction in serum LDL cholesterol levels of 4 - 5.5%. Given the normal variation in serum LDL cholesterol, smaller LDL reductions may not reach



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statistical significance, thus at least 8-11 g of SFAs appears to be the required level of replacement for effect. The condition of use of the health claim needs to define the daily amount of SFAs that shall be replaced and the consumer should be guided how to achieve this replacement based on the use of commercial food products.

The claimed effect needs to be obtainable with customary daily intake of the food product bearing the claim

The Regulation stipulates that the claimed effect needs to be achieved with a customary daily intake of the food. E.g. a commercial Finish low-fat spread (35% fat) contains 6.7 g SFAs, 16.3 g cis-MUFAs and 10.5 g cis-PUFAs/100g product. Based on normal consumption patterns, daily intakes of higher than 25 g spread per day can hardly be recommended. In order to reach a daily replacement of at least 8-11 g of cis-MUFAs and cis-PUFAs a daily intake of about 40-55 g of this particular spread is needed*. This means that in order to reach a significant cholesterol lowering the consumer need to switch from consuming 25g butter daily to 40-55 g of this particular low fat spread.

Example of comparison between food categories

A branded soymilk: 35 kcal/100 ml, 2.2 g fat of which 0.4 g SFAs, consequently 1.8 g unsaturated fatty acids (81.8% of fatty acids present, 46 E-% of the product). Thus this soymilk fulfils the provision for the high unsaturated fat claim. In order to replace 8-11 g SFAs obtainable from 25 g/day butter the daily consumption of the soymilk need to be 570 -786 ml.

Hence Raisio suggests the condition of use to be amended to quantify the amount of SFAs in g/day that needs to be replaced by cis-MUFAs and/or cis-PUFAs. EU Commission must also define the type of comparison that is allowable. In addition EU Commission should consider if the product compared to should be stated in the labelling.

Importance of informing the consumer about the LDL lowering effect of the product

Certain food products with added plant sterols, plant sterol ester and plant stanol ester can provide additional information in the labelling that 1.5 - 2.4 g plant sterols or stanols reduce cholesterol by 7 - 10%, within 2 to 3 weeks. The consumer will most probably assume that all foods bearing the same art. 14 cholesterol lowering health will be equally effective in lowering blood cholesterol. In order to provide important information to the consumer, allowing them to make informed choices, it would be prudent that all food products bearing an art. 14 cholesterol lowering claim would state in the labelling the extent of cholesterol lowering the product will provide when consumed in recommended amounts. The cholesterol lowering effect shall be based on an EFSA evaluation.

* 40 g spread provides 2.7 g SFAs, 6.5 g cis-MUFAs and 4.2 g cis-PUFAs.



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Cholesterol lowering effect of replacing SFAs by cis-MUFAs and/or cis- PUFAs when already on a "balanced and varied diet"

The Regulation art 10(2)a states that health claims are only permitted if a statement indicating the importance of a varied and balanced diet and a healthy lifestyle is included in the labelling of the food. The Regulation does however not define what is meant by a varied and balanced diet. It is questionable if the cholesterol lowering benefit would be achievable by replacing SFAs by MUFAs and/or PUFAs by a person who adheres to a balanced and varied diet. Hence, a definition for "balanced and varied diet" is needed.

The Regulation and art. 14 health claims for diets

According to Article 1(2) of the Regulation the Regulation "*apply to nutrition and health claims made in commercial communication, weather in the labelling, presentation or advertising of foods to be delivered as such to the final consumer.*" (Emphasise added). "Diets" does not fall under the definition of "food" as set out by Article 2 of regulation EC No 178/2002 of the European parliament⁶.

Further under Article 5(3), *General conditions* in the Regulation the following is stated: "*Nutrition and health claims shall refer to the food ready for consumption in accordance with the manufacturer's instructions*" (Emphasise added). This general condition would not be fulfilled if the claim is for a diet. Hence, it appears that "diets" cannot be covered by the proposed health claim.

Difference between art. 13 ("cholesterol maintenance") and art. 14 health claims ("cholesterol reduction")

The condition of use set by EFSA on a corresponding art 13 health claim⁷ is the same as the condition of use now proposed for the art. 14 health claim, even though the Regulation clearly distinguishes between the two types of health claims. We question if the condition of use can be the same for both an art. 13 and an art. 14 health claim covering the same ingredient or food.

All claims where the scientific substantiation for the health claim by EFSA is based on reducing a disease risk factor such as blood pressure or cholesterol should apparently be classified as art 14. claims.

We urge that the EU Commission should decide whether art. 13 "maintenance of normal cholesterol" health claims are scientifically founded and if indeed these health claims are art. 14 disease risk reduction health claims based on the ruling of the EU Commission as art. 13 "maintenance of normal cholesterol" health claims require scientific evidence of a cholesterol lowering effect versus appropriate control in order to obtain a positive EFSA opinion.



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Mandatory warning labelling puts foods with added plant sterols or plant stanols in an unfavourable position

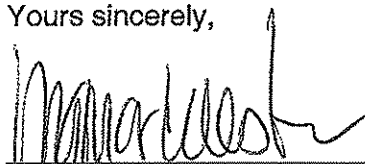
Labelling that is mandatory for food products with added plant stanols or plant sterols, has not been suggested in other positive EFSA opinions related to art. 14 coronary heart disease risk reduction claims. This will undoubtedly lead to unfair competition and induce confusion amongst consumers, as the consumer will find a cholesterol lowering product free of warning statements more attractive.

We therefore urge the EU Commission to consider the unfair competition that will emerge if food products with art. 14 cholesterol lowering health claims are treated differently regarding mandatory "warning statements" and the quantifying of the cholesterol lowering effect. In order to prevent misleading consumers and the induction of unfair competition the EU Commission should seek ways of equal treatment that should be based on scientific evaluations of EFSA.

If EFSA finds that warning statements are still warranted and scientifically substantiated, the use of such warranted warnings labels need to be evaluated for each cholesterol lowering ingredient, on a case by case bases.

If you require further information, please do not hesitate to contact us.

Yours sincerely,



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References:

- 1 EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) ; Scientific Opinion on the substantiation of a health claim related to "low fat and low trans spreadable fat rich in unsaturated and omega-3 fatty acids" and reduction of LDL-cholesterol concentrations pursuant to Article 14 of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(5):2168. [13 pp.]. doi:10.2903/j.efsa.2011.2168.
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Available online at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:012:0003:0018:EN:PDF>
 - 3 COMMISSION REGULATION (EU) No 116/2010 of 9 February 2010 amending Regulation (EC) No 1924/2006 of the European Parliament and of the Council with regard to the list of nutrition claims..
Available online at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:037:0016:0018:EN:PDF>
 - 4 Hendriks HFJ, Westrate JA, van Vliet T, Meijer GW. Spreads enriched with three different levels of vegetable oil sterols and the degree of cholesterol lowering in normocholesterolaemic and mildly hypercholesterolaemic subjects. *Eur J Clin Nutr* 1999; 53: 319-327.
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 - 7 EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to the replacement of mixtures of saturated fatty acids (SFAs) as present in foods or diets with mixtures of monounsaturated fatty acids (MUFAs) and/or mixtures of polyunsaturated fatty acids (PUFAs), and maintenance of normal blood LDL-cholesterol concentrations (ID 621, 1190, 1203, 2906, 2910, 3065) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. *EFSA Journal* 2011;9(4):2069. [18 pp.].
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