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Brussels, 24th June 2011

Dear Basil,

We welcome the recently published European Food Standards Authority (EFSA) Scientific Opinion (Q No 2009-00458) 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.

We agree that the wording proposed by EFSA reflects the scientific evidence. We are also happy that EFSA indicates that for a cholesterol reduction claim it is not sufficient to have low SFA product only, but that the fat quality or amount of unsaturated fat versus amount of saturated fat should be taken into account on a per gram fat basis.

However, we would like to share our concerns specifically on the proposed conditions of use:

- 1) Under the proposed conditions, replacing saturated fat (SFA) with only monounsaturated fat (MUFA) would be sufficient to carry a cholesterol reduction and heart disease risk reduction claim. This is in contrast with the current scientific consensus that SFA should be replaced with polyunsaturated fat (PUFA) rather than MUFA to lower the risk of heart disease which was also acknowledged in the EFSA opinion on dietary reference values. We therefore propose that a minimum ratio of SFA versus PUFA and MUFA in the product that carries a cholesterol reduction claim for products.
- 2) There is no minimum specified for the amount of PUFA or MUFA that should be delivered in a product. This is in contrast with other EU health claims that have been approved such as ‘Essential fatty acids are need for normal growth and development of children’. These claims are required to provide a minimum amount of linoleic acid(LA) and alpha-linolenic acid (ALA) to make the claim and we propose that the same should be required with this claim.
- 3) In addition the Commission should establish as a matter of priority specific nutrient profiles which foods or certain categories of food must comply with in order to bear specific nutrition or health claims.

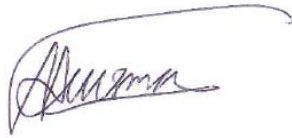
We believe it is important that these three conditions are taken into consideration otherwise many foods that currently are not advised as heart healthier options in national dietary

recommendations will be allowed to carry a cholesterol reduction claim and/or a heart disease risk reduction claim.

It is worth noting that by adding these additional requirements in the conditions of use could result in a composition that is close to the conditions of use as initially proposed by the applicant Lactalis.

We hope that the Commission is willing to take our concerns and suggestions into consideration. Please do not hesitate to contact me should you require any further information.

Yours sincerely,

A handwritten signature in blue ink, appearing to read 'Truus Huisman', with a long, sweeping horizontal flourish extending to the right.

Truus Huisman

## Appendix with details on various aspects of the letter

Wording proposed by EFSA for claim No Q2009-000458:

*“Consumption of saturated fat increases blood cholesterol concentrations; consumption of mono- and/or polyunsaturated fat in replacement of saturated fat has been shown to lower/reduce blood cholesterol. Blood cholesterol lowering may reduce the risk of (coronary) heart disease”.*

Conditions of use proposed by EFSA for claims No Q2009-000458

*‘ 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.’* These conditions of use as proposed would mean that , when compared with a food in the same product category, any food that has 30% less SFA could be replaced by the corresponding amount of either MUFA or PUFA and be allowed to carry a cholesterol reduction and heart disease reduction claim. Such products would not necessarily be in line with dietary guidelines for a healthier heart. Using the criteria outline above would mean that the following foods could make a cholesterol reduction and heart disease reduction claim:

- High fat meat products where MUFA has been added in processing to result in 30% lower SFA levels in the fat content rather than lean meat varieties recommended.
- Full fat dairy products where MUFA has been added in processing to result in 30% lower SFA levels in the fat content rather than lower fat dairy products that are recommended.

Scientific consensus that SFA should be replaced with PUFA rather than MUFA to reduce cardiovascular disease risk.

Quote from FAO report. Fats and fatty acids in Human Nutrition. Report of an Expert Consultation No 91 FAO 2010

*There is **convincing** evidence that replacing SFA with PUFA decreases the risk of CHD.*

*There is insufficient evidence relating to the effect on the risk of CHD in replacing SFA with either MUFA or largely whole grain carbohydrates; however, based on indirect lines of evidence this could result in a reduced risk of CHD.*

Quote from EFSA opinions on dietary reference values for fats. Outcome of the Public Consultation on the Draft Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies (NDA) on Dietary Reference Values for fats, including saturated fatty acids, polyunsaturated fatty acids, monounsaturated fatty acids, trans fatty acids and cholesterol. EFSA Journal 2010; 8(5) 1507-232 .

*‘Cis- monounsaturated fatty acids are synthesised by the body, have no known specific role in preventing or promoting diet-related diseases, and are therefore not indispensable constituents of the diet. The Panel proposes not to set any Dietary Reference Value for cis-monounsaturated fatty acids’.*

Conditions of use from EU authorisation on Linoleic Acid (LA) and Alpha-Linolenic acid (ALA ) claims in Commission Regulation (EC) 983/2009 ,

*‘In order to bear the claim a food should contain at least 15% of the proposed labelling reference intake values of 10 g linoleic acid per day’; ‘ In order to bear the claim a food should contain at least 15% of the proposed labelling reference intake value of 2 g ALA per day’.* The absence of a minimum amount of PUFA would mean that products that have a very low fat content to begin with ( e.g. white bread) could suddenly make a cholesterol reduction claim by adding a bit of MUFA or PUFA to get to a 30% lower SFA in total fat.

Proposed guidance on the minimum ratio of SFA versus PUFA & MUFA in the product that carries a cholesterol reduction claim.

The scientifically well documented and generally accepted Mensink<sup>1</sup> equation could be used to judge if a food with a cholesterol reduction claim would result in cholesterol reduction when the food replaces carbohydrates in the diet.

Alternatively, a simpler guidance could be used that would bring the fat composition of a product carrying the claim in line with the advice in dietary recommendations ( e.g. FAO expert report 2010) : max 30% of the fat in the diet should come from SFA or from SFA + TFA.

Proposed requirement that a product carrying a claim should deliver a minimum amount of omega 3 and omega 6 PUFA.

In this respect the conditions of use that are already in place for cholesterol maintenance claims mentioned above could be used (15 % of the labelling reference for LA and ALA), or alternatively the guidance for a ‘high PUFA’ nutrition claim could also be used.  
Commission Regulation (EC)116/2010

1.Mensink RP, Zock PL, Kester ADM, Katan MB. Effects of dietary fatty acids and carbohydrates on the ratio of serum total to HDL cholesterol and on serum lipids and apolipoproteins: a meta-analysis of 60controlled trials. Am J Clin Nutr 2003; 77:1146-55