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3 April 2012

**PA1070 – items in the application which require clarification.  
 28 march 2012**

Dear Lynne

I am writing to provide further information in response to your email request for clarification dated 28 March 2012. For clarity each bullet point has been cited as the heading, in *italics*, with the response below.

**Technical comments:**

***Page 7, paragraph 3 – the consumer purchase information mentioned in this paragraph is not referenced to a survey. Please provide a reference, and clarification on how the percentages were derived.***

Consumer purchase information is provided in Appendix 3 and, specifically in relation to the statements in paragraph 3, on page 3 which reports Total Live Active Cheese purchases - 26 Weeks To 14/05/2011, Source Nielsen | Homescan® (Australia).

***Page 9, 1<sup>st</sup> bullet point - FSANZ is aware of two further studies (Hearty A, et al, (2008), Public health Nutrition 12(1), 51-58 and Sioen I, et al, (2011), British Journal of Nutrition 105, 911-918). Commenting on and citing these studies as part of your evidence base, would enhance the Application.***

We have reviewed the two publications identified by FSANZ and have the following comments:

**Hearty et al. 2008. Phytosterol-enriched products on the Irish market: examination of intake and consumption patterns. Public Health Nutrition: 12(1), 51–58**

This study reported phytosterol intake by 468 consumers of phytosterol enriched products (186 men and 282 women) in The Republic of Ireland. The study subjects were recruited both urban and rural locations representing different socio-economic catchment areas. There were five enriched product types on the Irish market at the time of the study: spreads, yoghurt drinks, yoghurts, milk and cheese spread (within the European Union, phytosterol enriched products, including cheese, may be presented in multi-serve packages provided that they can be easily divided into portions that contain either a maximum of 3 g (in case of one portion per day) or a maximum of 1 g (in case of three portions per day) of added phytosterols/phytosteranols). Optimal phytosterol intake was considered to be in the range 1.5-3.0 g/day. The mean phytosterol intake was 2.45 g/d with the 95th percentile intake at 5.48g/day and 53% of consumers reporting phytosterol intake with the optimal range. Mean

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intake was significantly higher for men than women (2.71 g/d v. 2.29 g/d) and for consumers with a lower educational standard (completed third level (2.14 g/d) ,vs primary 2.81g/day and secondary 2.57/day). The study indicated that a majority of Irish consumers obtain their phytosterols from spread and yoghurt products with only 9 subjects (2%) reporting consumption of phytosterol enriched cheese spread. Only one consumer reported use of cheese spread as a sole source of phytosterols and only 3 of 106 consumers consuming phytosterols above the optimum level (>3.0 g/day) reported consuming an enriched cheese product. The highest reported daily phytosterol consumption by a consumer of enriched cheese products was 4.46g compared to a maximum of 9.84g/day for consumers of spreads and yoghurt drinks. Overall this study suggests that a small number of consumers currently recognise cheese products as an available vehicle for phytosterols and, furthermore, that these products are primarily consumed with other enriched products, within optimal guideline levels. Enriched cheese products, in multi-serve packaging, are largely consumed within guideline levels and do not have a significant role in super-optimal consumption, which appears to be more closely linked to consumption of enriched spreads and yoghurt products.

**Sioen et al (2011). Consumption of plant sterols in Belgium: estimated intakes and sources of naturally occurring plant sterols and b-carotene. British Journal of Nutrition , 105, 960–966.**

This study matched Belgian food consumption data for (1) pre-school children (2·5–6·5 years old) and (2) adults (>15 years old) with a data base containing the plant sterol and b-carotene content in all relevant food items. Foods enriched with plant sterols were excluded from the study. The study reported a median plant sterol intake of 172 and 184 mg/d, for preschool girls and boys, respectively, and 218 and 280 mg/d, for women and men, respectively. In all cases the reported level of natural consumption for phytosterols was substantially below the upper optimal limit for cholesterol lowering (3.0g/day) . The authors also reported that the results were similar to those reported for other European countries. The calculated median beta-carotene intake for both pre-school children and adults, were reported to be between 1800 and 1900 mg/d, from which the authors concluded that the contribution of beta-carotene to the recommended daily intake of vitamin A was favourable. This paper suggests that Belgian consumers of phytosterol enriched products, from either target or non-target populations are not exposed to risks associated with consumption of insufficient dietary beta-carotene. These findings support the FSANZ risk assessment prepared for application A1019 – Phytosterol esters in low fat cheese - section 5.4, which concluded that there are no overt nutritional issues associated with the reductions in serum carotenoid levels associated with the use of plant sterol fortified foods.

**Page 18** – please confirm that the reference to “Appendix 1” in the first paragraph should be Appendix 2. In addition, please clarify how the percentages, referred to in the first two paragraphs, were derived.

The reference in paragraph 1 page 18 is incorrectly identified as Appendix 1. The correct reference is Appendix 2.

**Page 18** - 2<sup>nd</sup> paragraph, last sentence, the objective of the statement “...whilst younger buyers are more likely to buy both phytosterol enriched and non-enriched products” is unclear to us. Please clarify.

The data presented in Appendix 1 includes purchase information on both LiveActive phytosterol enriched cheese and Philadelphia, an equivalent non-enriched cheese product. The data shows that older households who buy a LiveActive cheese product are less likely to also buy a non-enriched alternative (eg Philadelphia). Conversely, in younger households where a phytosterol enriched cheese is bought, the non-enriched product is also bought more frequently . This suggests that in the older household there is a higher incidence of all members eating the enriched product, whether they are members of the target group or not. However, in younger households, the suggestion is that the phytosterol enriched product may be bought for specific family members, with a non-enriched cheese product also purchased for other members of the household.

**Section 3.4** – please confirm our understanding that this section is aimed at addressing Section 3.6.1, C, 2, of the Handbook, “Information to demonstrate that the food(s) containing the novel food ingredient will not adversely affect any population groups (e.g. particular age or cultural groups)”. We note that some information about children has been provided; it would however enhance the Application if there was also discussion of effects on cultural groups, as well as the impacts on people in low socioeconomic groups. Information relating to the latter is mentioned earlier in the

application; this should be summarised into this section. The content around safety is irrelevant to this section.

Part 3 is intended to address Section 3.6.1 of the handbook. In relation to section C2 of the handbook, the efficacy of phytosterols in relation to cholesterol lowering is not defined or limited by race or socioeconomic group. Therefore, in section 3.4, Kraft has sought to address this requested for information in relation to the potential for adverse effects on populations, other than the target population (irrespective of race or socioeconomic status), and, specifically, those non-target population groups already identified through existing phytosterol risk communication labelling in the Code (i.e. children and pregnant and lactating women).

The intent of the application is to broaden the choice for consumers wishing to buy a phytosterol enriched food. There may be some increase in availability of phytosterol enriched cheese products in small and medium retail outlets and, together with a significantly lower unit cost, this may make the option of a phytosterol enriched cheese product more accessible to remote or regional populations. Kraft is not aware of any evidence suggesting that the amendment will have any adverse impact on:

1. the efficacy of advisory labelling targeted children and pregnant and lactating women as a risk management strategy, or
2. the availability of regular non-phytosterol enriched products or other phytosterol enriched products to non-target group consumers, regardless of racial group or socioeconomic status.

#### General comments:

**Appendices** – the list of Appendices on page 24 of the Application do not clearly match with the Appendices provided thereafter. Except for Appendix 4 (see next point), the Appendices are not numbered and the titles on them do not match with those given on page 24. Appendix 4, “Examples of presentation of cheese in 240g multi serve tub” appears to be incorrectly number Appendix 3 – “Mock up demonstrating.....”. Please provide better linkage between details on page 24 and the identification of the various appendices.

In the 2 hard copies supplied each appendix is preceded by a cover page stating its number and title matching that on page 24.

The following table indicates the relationship between the Appendices listed on Page 24 and in the document Appendices.pdf in the electronic copy, the individual names of the pdf documents in the zip file (Appendices.zip) in the electronic copy and the opening text of those documents:

Page 24 -Appendices & Appendices.pdf	Corresponding document in Appendices.zip	Opening text of document
Appendix 1 - customer inquiries liveactive cream cheese.pdf	Appendix 1 - customer inquiries liveactive cream cheese.pdf	Title : liveactive cream cheese VOICE Accounting Timeframe: Jan 2010 To Feb 2012 Product(s): 93650670 : PHILADELPHIA 160 GR CR Reason(s):(I) AVAILABILITY
Appendix 2 - Kraft_Cheese_Live Active and Philly duplication_29 11 2011.pdf (comparisons of sales for LiveActive and Philly and Philly in 4x40 vs 250g tubs)	Appendix 2 - Kraft_Cheese_Live Active and Philly duplication_29 11 2011.pdf	Kraft Foods. Live Active and Philly Unique appeal and overlap 29th November 2011
Appendix 3 - Moulton 2011	Appendix 3 Moulton 2011 .pdf	KRAFT LIVEACTIVE CHEESE Natasha Moulton September 2011

<b>Page 24 -Appendices &amp; Appendices.pdf</b>	<b>Corresponding document in Appendices.zip</b>	<b>Opening text of document</b>
Appendix 4 - Examples of presentation of cheese in 240g multi serve tub	Appendix 4 - multi serve tub presentation.pdf	Appendix 3 - Mock up demonstrating increased identity and visibility of proposed of multi serve LiveActive Light Cream Cheese tub (left) compared to current multi minitub package (right).
Appendix 5 -GNPD Plant Sterol Cheese.pdf ( <i>MINTEL search - examples of phytosterol enriched cheese product on sale in EU</i> ).	Appendix 5 - GNPD Plant Sterol Cheese.pdf	Mintel Products from GNPD Monitoring New Product Trends and Innovations
Appendix 6 – Communication of daily sterol requirement	Appendix 6 - Communication of daily sterol requirement - consumers are sophisticated.pdf	Proposed on-pack consumer messages on dosage control of phytosterols for multi-serve low-fat cream cheese
Appendix 7 - Barriers to cheese consumption	Appendix 7 - Barriers to cheese consumption.pdf	Where did the idea come from?

**Page numbers** - The page numbers in the contents page need to match those in the document. Currently the Contents page states the Executive summary is on page 2, whereas the page is labelled as “ii” in the document. Similarly it appears page “iii” should be “3”. Please clarify.

The page numbering in the application is continuous from the Contents on page 1 , the Executive summary on pages 2-3 and the body of the application starting on page 4. For differentiation, the preliminary documents are numbered using roman numerals and those from page 4 (the body of the application) using arabic numeral. This differentiation in formatting has not been recognised by the chapter management software used to compile the application and consequently all page numbers in the Contents Table are all shown in arabic numerals in the application. Consequently, page ii is shown as page 2 in the Contents Table.

**Section 2.1.1, Applicant, (b) address** – please provide a postal address.

The applicant's address is:

Kraft Foods Limited  
Level 6, South Wharf Tower  
30 Convention Centre Place  
South Wharf, Victoria 3006  
Australia

**Section 2.1.1, Applicant, (f) Nature of applicant’s business** – please provide this information.

Globally Kraft Foods Limited is the world’s second largest food company, making products in approximately 170 countries. Kraft Foods brands in Australia include; Vegemite, Philadelphia Cream Cheese, Cadbury Dairy Milk, The Natural Confectionery Co., Pascall Marshmallows, Cadbury Favourites, Cherry Ripe, Freddo Frog, Toblerone, Oreo, Kraft ‘Nuts’ Peanut Butter, Cadbury Roses and Kraft Natural Cheese.

**Appendix 2** – the values in the diagrams on pages 3-11 are difficult to read due to poor quality of the images. Please provide better quality images or clarification of the values.

The original powerpoint version of the document from which the pdf was printed is attached  
Appendix 2 -Kraft\_Cheese\_Live Active and Philly duplication\_29 11 2011- ORIGINAL.ppt

Brooke-Taylor & Co Pty Ltd are not lawyers and do not provide legal services or give legal advice.  
Any advice given in this letter is not intended as and should not be construed as legal advice. If you  
have any further questions on this or any other matter relating to our application please contact me  
as indicated below.

Yours sincerely

A handwritten signature in blue ink, appearing to read 'S. Brooke-Taylor', with a stylized flourish at the end.

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