

Food Standards Australia New Zealand  
PO Box 7186  
Canberra ACT.

07<sup>th</sup> May 2012

Dear Sir,

RE: Application A1065, Packaging Size for Phytosterol-enriched Milk

Raisio Nutrition Ltd. (later Raisio), the international manufacture of plant stanol ester commercially marketed under the Benecol brand since 1995, wish to support FSANZ in their accepting Application A1065 to remove the restriction on packaging size for milks enriched with phytosterols.

Cholesterol management, as FSANZ is well aware, is a huge cost to the public health system. During 2001, the top 10 prescription medicines by cost to the Commonwealth Government amounted to around \$1.4 billion of Commonwealth expenditure. Of this the top two ranked prescription medicines were drugs used to lower cholesterol. The Commonwealth spent \$539 million on Atorvastatin's and Simvastatin being 39% of the Commonwealth expenditure on the top 10 subsidised drugs this cost has escalated to over \$870 million in 2009 [www.health.gov.au](http://www.health.gov.au); Australians Statistics for Medicines

Phytosterols, as assessed by FSANZ (Approval Report Application A1024 – Equivalence plant Stanols, sterols and their fatty acid esters) are effective in cholesterol reduction when consumed regularly at the effective dosage level. Unfortunately as again noted by FSANZ, most consumers in Australia are unable to currently achieve the currently recommended 2-3 g daily intake, which has the potential to reduce serum Ldl-cholesterol levels by up to 15% when used continuously by individuals with elevated cholesterol levels.

#### **Q1. Safety Information**

Raisio, as does FSANZ, has a continual interest in reviewing all published scientific research into all aspects of safety, usage and consumption of phytosterol enriched products. Raisio is unaware of any new research highlighting negative safety issues, apart from the single article by Kelly et al (2011) cited by FSANZ, which have published since the safety information reviewed by FSANZ in the 2010 A1024.

Raisio commend FSANZ for their balanced assessment of the Kelly et al (2011) article, recognising the need to evaluate isolated research findings in context of their physiological relevance. However Raisio further want to stress that the possible concerns raised in the Kelly et al. (2011) study are only related to plant sterols and NOT to plant stanols.

## **Q2. Consumption Information**

FSANZ have in the past expressed concerns that non target populations for cholesterol reduction, particularly children and pregnant women could be exposed to over consumption of plant sterol products. This has resulted in the current limitations set in the Food Standards Code on the products permitted to include phytosterols and the concentrations available in those permitted products.

The range and amounts of phytosterol enriched products available to discerning consumers in Australia has therefore been very limited compared to the range available elsewhere. US FDA has not limited the range of food format to which phytosterols can be added as long as the food is GRAS.

The cholesterol lowering ingredient plant stanol ester is now available in over 150 different products worldwide (increased from the listed 115 products in A 1024 in 2009). Raisio has no record of any significant overconsumption in either at risk populations or even misuse amongst target populations (company information).

In 2006 in the UK an independent research company TNS investigated aspects of phytosterol usage for the UK Food Authority, particularly to understand who is consuming cholesterol lowering products, in what quantities and whether this consumption is within recommended limits (report confidential).

This report indicated that considering the frequency of consumption data, both claimed and actual, there is little over consumption, with 97% of consumers consuming twice a day or less. This finding should be viewed in context that the surveyed consumers have access to a broader range of products as compared to Australian consumers so they would have greater opportunity for a more varied consumption.

However, despite these increased opportunities there are indications that significant numbers of UK consumers may not be consuming enough of the products to gain a real benefit despite the extensive range of products they have access to.

Of particular interest to FSANZ may be the comment that the TNS survey found consumption amongst the under 5s to be very low, with this group accounting for barely measurable numbers of all phytosterol containing product consumption occasions.

The heavy consumers of phytosterol containing products are found to be aged 45 and older and more than half of them being females. Importantly there was no evidence in the report that the nutritionally inappropriate groups were among the heavy consumers, with no heavy consumption among children under 5 years old and women aged 17 – 44 years old (typical age for pregnant or breastfeeding women).



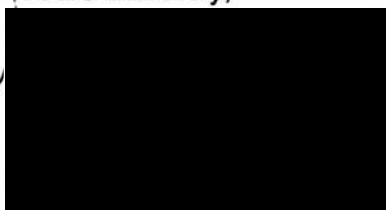
These findings underpin FSANZ confidence in the safety of increased availability of phytosterol enriched products.

### **Q 3 Cost benefits**

The public will get major benefits from the more economical size availability of phytosterol enriched milks.

Raisio Nutrition Ltd. urges FSANZ to adopt Application 1065 and consider further expansion of phytosterol enriched products so Australian consumers can gain similar nutritional advantage to their overseas colleagues.

Yours sincerely,



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