



Application to amend the
Australia New Zealand
Food Standards Code

Removal of package size
restrictions for milk with added
phytosterols, phytosterols
and their esters

July 2011

Application to amend the
Australia New Zealand Food Standards Code

PART 1	INTRODUCTION	3
1.1	Executive Summary	3
1.2	Checklist.....	5
1.3	Statutory Declaration	6
PART 2	GENERAL INFORMATION	7
2.1	Applicant Details.....	7
2.1.1	Applicant	7
2.1.2	Consultant	7
2.2	Purpose this Application.....	7
2.3	Justification for the Application.....	8
2.4	Information to Support the Application	10
2.4.1	Consumption of Phytosterols	10
2.4.2	International markets	12
2.4.3	Homogeneity.....	13
2.4.4	Potential consumption by young children	14
2.4.5	Cost/Benefit Analysis	17
2.4.6	FSANZ objectives.....	19
2.4.7	Applicant’s Objectives.....	20
2.4.8	Nutritional implications	20
2.4.9	Dietary implications	21
2.4.10	Advantage to the consumer.....	21
2.5	Assessment Procedure	21
2.6	Confidential Commercial Information	21
2.7	Exclusive Capturable Commercial Benefit.....	22

2.8	International and other National Standards	22
2.8.1	International Standards	22
2.8.2	National Standards.....	22
PART 3	REGULATORY IMPACT STATEMENT	26
3.1	Consumers.....	26
3.2	Industry.....	26
3.3	Government.....	26
PART 4	A NON-COMPOSITIONAL CHANGE TO A STANDARDISED FOOD	27
4.1	Information on consumer understanding and behaviour	27
4.2	Adverse health or diet impacts on population groups (e.g. age or cultural groups)	28
4.3	Information related to impact on the food industry	28
4.3.1	Projected cost to the food industry	28
4.3.2	Impact on international trade.....	29
REFERENCES	30
APPENDICES		
1.	Nielsen data and analysis.....	32
2.	Roy Morgan data.....	39
3.	Mintel Milk with plant sterols Global Sales	40
4.	Mintel Milk Sales UK.....	51
5.	Report of analysis.....	52

PART 1 INTRODUCTION

1.1 Executive Summary

(as per section 3.1.1 of the Application Handbook July 2010)

This Application is to remove the size restriction on packages of milk containing all types of phytosterols, phytostanols or their esters, for which the labelled volume is currently set at no more than 1 litre. This size restriction was imposed by the First Review Report for Applications A433, A434 and A508 in August 2005 and carried over to the Second Review Report in October 2006. The original recommendation made by FSANZ in relation to Application A434 in October 2004 did not impose a size restriction.

This Application is made to vary an existing Standard in the *Australia New Zealand Food Standards Code* (the Code); Standard 2.5.1 – Milk.

This Application is made by National Foods, producers of Pura and Dairy Farmers HeartActive, 1 litre plant sterol enriched milk.

Standard 2.5.1 currently states in clause 5 as follows:

5 Phytosterols, phytostanols and their esters

Phytosterols, phytostanols and their esters may only be added to milk –

(a) that contains no more than 1.5 g total fat per 100 g; and

(b) that is supplied in a package, the labelled volume of which is no more than 1 litre; and

(c) where the total plant sterol equivalents content is no less than 3 g/L of milk and no more than 4 g/L of milk.

This Application is to delete subclause 5 (b).

Deletion of subclause 5 (b) would allow for larger containers of milk that contains phytosterols, phytostanols or their esters¹ and no more than 1.5 g total fat per 100g. Phytostanols are permitted to be added to milk as a consequence of the change to the drafting of the Standard as a result of consideration of the equivalence of phytosterols in Application A1024.

¹ Note: phytosterols, phytostanols or their esters will be referred to as ‘phytosterols (or their equivalents)’ in this Application.

Deletion of subclause 5 (b) would allow for larger than 1 litre sized packages of HeartActive milk – as requested by consumers of the product to National Foods' Consumer Enquiry Centre.

Removing this restriction would create a more harmonised international regulatory outcome with our international trading partners. No restriction on a package size for milk is required in legislation anywhere else in the world, including the European Union (EU) and the United States of America (USA).

There is no safety concern associated with consumption of foods currently permitted to contain phytosterols (or their equivalents), and no acceptable daily intake (ADI) has been established for phytosterols (or their equivalents) in Australia and New Zealand.

As concluded in FSANZ's assessment report for Application A1019: A comprehensive review of the literature does not indicate any population health risk arising from consumption of plant sterol fortified foods.

The risk assessment for A1019 concluded that there is likely to be a very small proportion of children (2-3%) aged 2-16 years who consume phytosterol-fortified products. Data on consumer purchases of milk supports the conclusion in A1019. Phytosterol enriched milks are targeted at people with elevated blood cholesterol levels and these people are mainly in the age group from 40 to 64 years old.

The Final Assessment Report for Application A434 recommended approval of the request to add phytosterols to milk and did not include any restrictions on package sizes. The packaging restrictions were raised in the First Review Report for three phytosterol related applications at a time when jurisdictions were not required to provide justification for such reviews and when a single jurisdiction could ask for a review.

There is no public health-based justification for maintaining the restriction on package size for milk enriched with phytosterols (or their equivalents).

1.2 Checklist

(from the Appendix of Application Handbook)

General Requirements *(as per section 3.1 of the Application Handbook July 2010)*

- ☒ Form of Application
- ☒ Relevant sections of part 3 identified
- ☒ Pages sequentially numbered
- ☒ Hard copies capable of being laid flat
- ☒ Electronic and hard copies identical
- ☒ Executive Summary
- ☒ Assessment procedure
- ☒ Applicant details
- ☒ Confidential Commercial Information
- ☒ Purpose of the Application
- ☒ Exclusive Capturable Commercial Benefit
- ☒ Justification for the Application
- ☒ International standards
- ☒ Information to support the Application
- ☒ Statutory Declaration

Standardised Foods *(as per section 3.6.1 of the Application Handbook July 2010)*

- ☒ Proposed compositional change
- ☒ Potential adverse health or diet impacts
- ☒ List of foods likely to be affected
- ☒ Impact on the food industry
- ☒ Nutritional content of standardised food
- ☒ Impact on trade
- ☒ Demonstrated consumer understanding of proposed change

1.3 Statutory Declaration

(as per section 3.1.10 of the Application Handbook July 2010)

Statutory Declarations Act 1959 - As per section 3.1.10 of the Application Handbook July 2010

I, Janine Waller, Nutrition Manager of National Foods, 737 Bourke St Docklands Vic 3008
make the following declaration under the Statutory Declarations Act 1959:

1. the information provided in this application fully sets out the matters required;
2. the information is true to the best of my knowledge and belief; and
3. no information has been withheld which might prejudice this application, to the best of my knowledge and belief.

I understand that a person who intentionally makes a false statement in a statutory declaration is guilty of an offence under section 11 of the Statutory Declarations Act 1959, and I believe that the statements in this declaration are true in every particular.

Declared at Melbourne [Place] on 26 [day] of July 2011 [month][year]

Before me,



[Signature of person before whom the declaration is made]*

[Full name, qualification and address of person before whom the declaration is made (in printed letters)]

Katrina Brighton
Australian Legal Practitioner
737 Bourke Street
Docklands VIC 3008

PART 2 GENERAL INFORMATION

2.1 Applicant Details

(as per section 3.1.2 of the Application Handbook)

2.1.1 Applicant

- (a) Janine Waller
 National Foods
- (b) 737 Bourke St Docklands, Vic 3008 or
 PO Box 6089 Melbourne Vic 3004
- (c) Phone: (03) 91886302 or 0409 189 574
- (d) Fax: (03) 91886303
- (e) Email: janine.waller@natfoods.com.au

2.1.2 Consultant

- (a) Jim Gruber
 Food Liaison Pty Limited;
- (b) Box 7336, Canberra MC, ACT, 2610, Australia
- (c) Phone: (02) 6297 8000
- (d) Fax: (02) 6297 8800
- (e) Email: jg@foodliaison.com.au
- (f) Internet: www.foodliaison.com.au

2.2 Purpose this Application

(as per section 3.1.3 of the Application Handbook)

This Application is intended to remove the current restriction on package size to allow for a more convenient and cost effective delivery of milk enriched with phytosterols (or their equivalents) to consumers and to increase choice in terms of the amount of product they desire to purchase in order to obtain the health benefits.

Consumers want a larger pack size for phytosterol enriched milk as demonstrated by requests to National Foods (from July 2010 to April 2011). There are no increased safety concerns about the consumption of phytosterols in the permitted food categories so there is no public health-based justification for the current restriction.

Removing the current restriction on pack size for milk enriched with phytosterols (or their equivalents) in Australia and New Zealand will also provide consistency in regulations for Australia and New Zealand with regulations in the USA and Europe. The Applicant has not been able to find this regulatory restriction anywhere apart from Australia and New Zealand.

2.3 Justification for the Application

(as per section 3.1.4 of the Application Handbook)

Milk is an effective vehicle for delivery of phytosterols, lowering serum cholesterol levels by up to 15% (FSANZ's 2nd review report for Applications A433, A434 and A508). Milk was found to be the most effective vehicle of the foods considered in Application A434 and the risk assessment for Application A1024 reconfirmed FSANZ's conclusion of 2005.

Standard 2.5.1 – Milk, subclause 5(b) is an unjustified restriction on package size, which in effect does not permit the sale of milk enriched with phytosterols (or their equivalents) in a container any larger than 1 litre.

Consumers are advised to drink two to three serves of phytosterol enriched milk per day to gain the proposed health benefit in terms of lowering levels of serum cholesterol. The National Heart Foundation's Position Statement on phytosterol/phytostanol enriched foods (2009) advises that plant sterols are most effective if we eat two to three grams per day and that this is roughly equivalent to two to three serves of foods containing plant sterols. As a serve of milk is 250mL, a 1 litre container will only provide the proposed benefits for a single consumer for one to two days.

National Foods sells phytosterol enriched milk in Australia in one litre containers, but does not currently market phytosterol enriched milk in New Zealand. Other companies do not appear to sell phytosterol milk in New Zealand, and this is confirmed by Nielsen data.

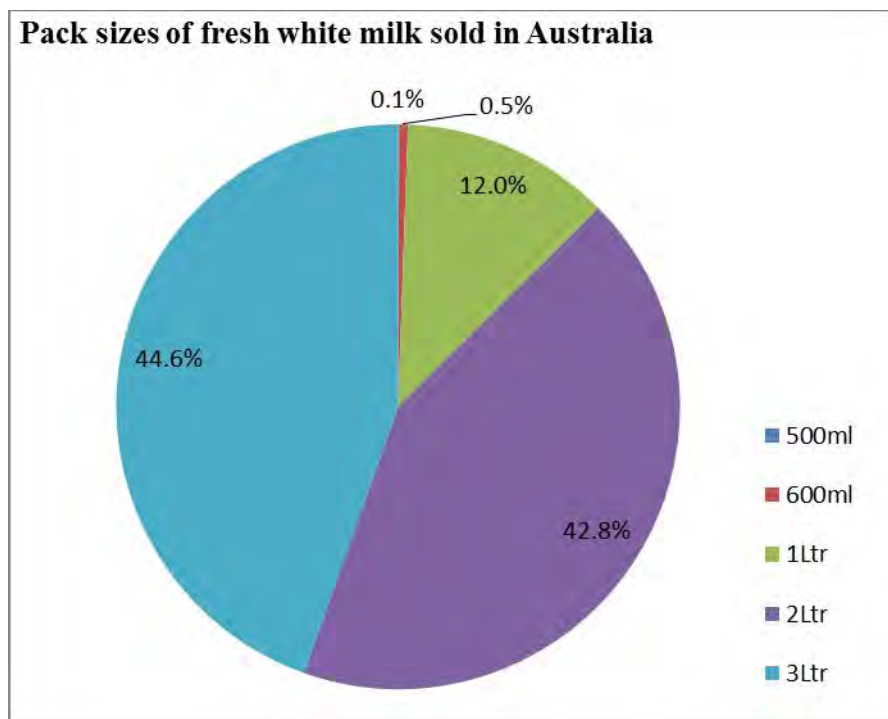
National Foods' Consumer Enquiry Centre has received a significant number of requests for a larger pack size of HeartActive phytosterol enriched milk. 14.6%² of consumer enquiries and feedback from July 2010 to April 2011 on phytosterol enriched milk have been about a larger pack size. The majority of other requests about this product have been about where to find the product, as 1 litre milk products have limited shelf space allocations.

Most consumers are generally buying milk in larger pack sizes (see Figure 1). Sales of milk in 1 litre containers are 12% of the volume sold while 2 and 3 litre containers account for 87.4% of the volume sold [National Foods calculation based in part on data reported by Nielsen through its ScanTrack service for the Milk Category, fresh white milk segment for the 52-week period ending April 03, 2011, for the Australian total grocery market (Copyright

² Note: Based on 24 enquiries relating to pack size out of a total of 164 enquiries

© 2011, Nielsen)]. This situation may be affected by current discounting of some milk in larger container sizes.

Figure 1



[National Foods calculation based in part on data reported by Nielsen through its ScanTrack service for the Milk Category, fresh white milk segment for the 52-week period ending April 03, 2011, for the Australian total grocery market (Copyright © 2011, Nielsen).]

Similarly in New Zealand packs greater than one litre are more popular and constitute 71% of the market.

Figure 2 - Fresh White Milk sales in supermarkets in New Zealand to 27 March 2011

	Vol Sales (Litres)	Unit % Share
Total FRESH MILK	199,002,045.6	100.0
0-300ML	410,695.5	1.3
one litre	29,109,858.0	26.7
2 LITRE	128,409,878.1	58.7
3 LITRE	39,928,512.2	12.2
301-600ML	646,833.7	1.0
4 LITRE	480,956.0	0.1
601-750ML	15,312.1	0.0

In the past 12 months, HeartActive buyers have allocated 79.9% of their milk purchasing volume to regular milk (38.9% to reduced fat milks, 34% to full fat milks and 7% to no fat milks), with only 20.1% to HeartActive milk containing phytosterols. [National Foods calculation based in part on data reported by Nielsen through its Nielsen Homescan for the Milk Category, fresh white milk segment for the 52-week period ending May 14, 2011 (Copyright © 2011, Nielsen)].

The average consumer does not know that there is a legislative restriction on package size to no more than 1 litre for phytosterol enriched milk. Explaining this labelling restriction to consumers is very difficult and trying to explain that it is a legislative restriction can cause some angst, even though there are no known safety concerns.

It is also important to note that the Final Assessment Report for Application A434 from Dairy Farmers recommended approval of the request to add phytosterols to milk and did not include any restrictions on package sizes. The packaging restrictions were raised in the First Review Report for three phytosterol related applications at a time when jurisdictions were not required to provide justification for such reviews and when a single jurisdiction could ask for a review.

2.4 Information to Support the Application

(as per section 3.1.5 of the Application Handbook)

2.4.1 Consumption of Phytosterols

FSANZ has established in consideration of Applications A433, A434 and A508 that the permitted range for phytosterols added to milk is based on efficacy and not on any safety concerns. The evidence indicates that consuming phytosterols in amounts above approximately 3 g/day does not improve the cholesterol lowering effects (FSANZ Final Assessment Report (FAR) A434). Neither the maximum amount of phytosterols, nor the restriction to 1 litre on pack size is based on safety concerns about phytosterols.

Monitoring in Europe has demonstrated that consumers have been responsible in their purchase of phytosterol enriched milk, with little evidence of over-consumption of food products with added plant sterols (EFSA Consumer Report on Phytosterols 2008).

This same responsibility in purchases of HeartActive is evident in Australia. In the past 12 months, HeartActive buyers have allocated 79.9% of their milk purchasing volume to regular milk (38.9% to reduced fat milks, 34% to full fat milks and 7% to no fat milks), with only 20.1% to HeartActive milk containing phytosterols [National Foods calculation based in part on data reported by Nielsen through its Nielsen Homescan for the Milk Category, fresh white milk segment for the 52-week period ending May 14, 2011 (Copyright © 2011, Nielsen)]. Refer to Appendix 1 for the Nielsen Data.

100% of HeartActive buyers purchased either other reduced fat/ full fat or both, milk alternatives [National Foods calculation based in part on data reported by Nielsen through its Nielsen Homescan for the Milk Category, fresh white milk segment for the 52-week period ending April 16, 2011 (Copyright © 2011, Nielsen)]. Therefore, it is apparent that phytosterol enriched milk is purchased specifically for the purpose intended.

81.9% of HeartActive buyers live in households with a medium to high income [National Foods calculation based in part on data reported by Nielsen through its Nielsen Homescan for the Milk Category, fresh white milk segment for the 52-week period ending April 16, 2011. (Copyright © 2011, Nielsen)]. This shows that plant sterol enriched milk doesn't attract low income buyers.

Roy Morgan market research (refer to Appendix 2) indicates that:

- People consuming HeartActive over-index³ in the age group of 50 years and older compared to the total population [Source: Roy Morgan Single Source (April 09 – March 11) n=189].
- 25.8% of HeartActive buyers live in household with a total income of \$120,000 or higher. Compared to the total population, this group represents only 17.2% which indicated HeartActive attracts more consumers with a higher total household income [Source: Roy Morgan Single Source (April 09 – March 11) n=314].
- More HeartActive consumers (82%, indexed against the total population of 127) live in households with no children compared to 64.4% of the total population [Source: Roy Morgan Single Source (April 09 – March 11) n=189].
- 70.1% of HeartActive consumers are 35 years or older and don't have children (47.5% are married, 35+ and no children; 22.6% are single, 35+ and no children) [Source: Roy Morgan Single Source (April 09 – March 11) n=189].
- HeartActive consumers are more likely to be overweight or obese (70.3% vs. 59.1% total population) [Source: Roy Morgan Single Source (April 09 – March 11) n=189].
- The majority (67%) of HeartActive consumer are concerned about their cholesterol levels. This over-indexes highly (n=178) compared to the total population among which only 37% voiced concerns about their cholesterol levels [Source: Roy Morgan Single Source (April 09 – March 11) n=189].

³ Overindex = the group is represented higher than the average population.

The price premium is another factor that would preclude general use of phytosterol enriched milk. On average, HeartActive milk containing phytosterols costs \$2.80 per litre compared to \$2 per litre (+40%) for an average litre of regular fat milk and \$2.10 (+33.3%) for a litre of reduced fat milk [National Foods calculation based in part on data reported by Nielsen through its ScanTrack service for the Milk Category, fresh white milk segment for the 52-week period ending June 05, 2011, for the Australian total grocery market (Copyright © 2011, Nielsen)].

Pack size restrictions do not apply to all other categories of plant sterol enriched foods in Australia. For example, 'Edible Oil Spreads' are permitted in Standard 2.4.2 to contain phytosterols (or their equivalents), with no pack restrictions stipulated. This means a typical 500 g tub of edible oil spread can contain fifty serves of 10 g. A 2 litre pack of milk would contain only eight serves of 250 mL and a 3 litre pack only twelve serves.

Standard 2.5.3 restricts the pack size for yoghurt with added phytosterols (or their equivalents) to 200 g.

In the FAR for A434, FSANZ concluded that specifying the maximum container sizes for the phytosterol enriched foods considered in the Application, i.e. milk and yoghurt, "discourages general household use by only permitting smaller quantities of foods that better suit individual use, rather than family use".

FSANZ explained that "allowing single serve tubs of yoghurt up to a maximum weight of 200 g provides manufacturers with some product flexibility to cater to the target group, but also helps consumers monitor the number of serves of phytosterol esters consumed in a day to ensure quantities are effective".

Phytosterol enriched milk was restricted to an arbitrary 1 litre container size, providing four serves of plant sterol enriched food. The statement above regarding yoghurt clearly does not apply to 1 litre cartons of phytosterol enriched milk and the same logic was not applied to edible oil spreads. Both milk and edible oil spreads are often used as ingredients throughout the day as opposed to a product such as yoghurt which is better suited to individual use and often consumed in one sitting.

Consumers of HeartActive have asked National Foods for larger packages of the product and consumers are being advised to drink two to three serves of phytosterol enriched milk per day to gain the proposed benefits in terms of lowering blood cholesterol levels. A package size restriction to four servings was not justified for milk enriched with phytosterols (or their equivalents). Evidence from Europe indicates that consumers are not consuming enough phytosterols to gain the proposed benefits (EFSA Consumer Report on Phytosterols 2008).

2.4.2 International markets

Milk products containing phytosterols (or their equivalents) are permitted in Europe and many other countries with no restriction on pack sizes.

Data from Mintel (refer to Appendix 3) provides information on the global sales of milk products containing phytosterols (or their equivalents) since 2000.

This data demonstrates that 33 new milk products containing phytosterols (or their equivalents) have been released around the world.

Phytosterol enriched milk products in half gallon (US) containers (1.9 litres) are widely available from Kroger stores in the USA as demonstrated in the following text from the CoroWise™ website (<http://www.corowise.com/wheretobuy/>).

“The Kroger Company is committed to providing customers with the products they need and want to make their lives better and healthier. The new Active Lifestyle Fat Free Milk with CoroWise™ plant sterols is one example of this commitment. The product is available in a half-gallon size nationwide in Kroger and Kroger Marketplace as well as local banner stores such as Ralphs, Fred Meyer, Food 4 Less, King Soopers, Smith's and Smith's Marketplace, Fry's and Fry's Marketplace, Dillons, QFC and City Market.

Foods containing at least 0.4 grams per serving of plant sterols, eaten twice a day with meals for a daily total intake of at least 0.8 grams, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease.”

There are a number of other phytosterol enriched products which are also advertised on the CoroWise™ website that are sold in larger multiple serve packs in the USA.

Galliker sells a similar pack of Healthy Chekd Fat Free Milk with phytosterols.

Minute Maid orange juice with phytosterols is sold in half gallon containers. Kroger stores also sell loaves of bread containing phytosterols.

Appendix 4 contains sales figures of milk in the United Kingdom for 2005-2009 (sourced from Mintel). In 2009, plastic bottles accounted for 82.9% of the market, and containers greater than 2 pints (about 1 litre) accounted for almost 60% of the market.

Similarly to the Australian and New Zealand markets, the preference in the United Kingdom's market is for larger packs of milk. Unfortunately, there is no available data on phytosterol enriched milk in the UK.

2.4.3 Homogeneity

National Foods has been selling phytosterol enriched milk for over four years since the launch in October 2006, with no customer complaints recorded about loss of homogeneity in the product. Analysis of the composition of the individual and total phytosterols in four

samples taken at different times from a factory trial confirmed that the product is homogeneous (see Appendix 5 - Report of Analysis). The composition of HeartActive in 1 litre packages remains stable over the storage life of the product (up to 40 days). Factory trials will be run and storage testing will be undertaken on products in bigger packages to ensure that the products remain homogeneous over their shelf life.

FSANZ suggested that examples of commercially unacceptable problems include having lumps or aggregations of plant sterols form in the food, discolouration or odour problems of the food and phase separation between the food and the added plant sterol (FSANZ FAR A434).

This can be a problem in products which separate on storage such as orange juice, but in milk the phytosterols are associated with the milk fat, which remains homogeneous and any separation can be visually or physically monitored. Phytosterols and phytosterol esters are known to be stable to both oxidation and heat, and remain relatively unchanged during milk processing, including the various pasteurisation treatments used to produce milk products. The processes used by National Foods for extended shelf life milk comply with the requirements of the Australia New Zealand Food Standards Code.

FSANZ acknowledged that there are likely to be some technical issues around incorporating some forms of plant sterols into certain foods to achieve uniform distribution but there is a range of technical solutions to this issue. The risk assessment indicates that technical solutions do exist to overcome these issues (FSANZ FAR A1024).

In addition, commercial realities are such that it is unlikely that a manufacturer will add an unsuitable plant sterol preparation to a food, which would lead to detrimental appearance, odour or flavour effects.

FSANZ considers that these two realities i.e. the requirement to produce a product which consistently meets the regulatory limits of plant sterol addition and one which is commercially acceptable, will ensure that only those plant sterol preparations which are suitable for addition will be added to permitted foods.

2.4.4 Potential consumption by young children

There are labelling requirements for foods enriched with phytosterols (or their equivalents). There may be some consumption by people outside the target group, including young children.

Standard 1.2.3 requires that the label of 'foods containing added phytosterols, phytostanols or their esters' include three advisory statements to the effect that;

- the product should be consumed as part of a healthy diet

- the product may not be suitable for children under the age of five years and pregnant or lactating women
- plant sterols do not provide additional benefits when consumed in excess of three grams per day.

FSANZ addressed this issue in the assessment of previous applications relating to phytosterol and phytostanol enriched foods.

As concluded in FSANZ's assessment report for Application A1019: A comprehensive review of the literature did not indicate any population health risk arising from consumption of plant sterol fortified foods. Based on an analysis of all toxicological information, FSANZ found no justification for establishing an ADI for plant sterols.

Application A1019 also concluded that there is likely to be a very small proportion of children (2-3%) aged 2-16 years who consume phytosterol-fortified products. Phytosterol enriched milks are however, targeted specifically to people at risk of high blood cholesterol levels and current data on consumer purchases of milk further supports the conclusion in A1019. There is also a labelling requirement specifying that the product may not be suitable for children under the age of 5 years.

“A survey of New Zealand and Australian consumers found that users of phytosterol-enriched margarines in the target group use the products in moderation and for the appropriate health reasons. Post-market monitoring in Europe, where a broader range of phytosterol-enriched foods has been available for some time, shows that consumers welcome choice of products, and over-consumption does not occur” (from FSANZ 2nd review report on Applications A433, A434 and A508).

The European Food Safety Authority (EFSA) surveyed consumers on their consumption of phytosterol enriched foods. The report concluded that to date, there appears to be little over-consumption of food products with added plant sterols. Rather, some consumers aren't eating enough of these products to gain a real health benefit (EFSA Consumer Report on Phytosterols 2008).

In the FAR to A434 FSANZ committed to collaborate with the National Heart Foundation of Australia in broadly based education activities that will significantly increase the visibility of information on plant sterols in the context of heart-healthy nutrition and dietary advice.

FSANZ also committed to prepare its own educational material on phytosterol-enriched foods suitable for wide distribution to professional organisations and the general public, linking to other sources of information on plant sterols (FSANZ FAR A434).

78.1% of HeartActive volume comes from households that have no children present [National Foods calculation based in part on data reported by Nielsen through its Nielsen Homescan for the Milk Category, fresh white milk segment for the 52-week period ending April 16, 2011 (Copyright © 2011, Nielsen)].

National Foods actively markets to the target audience of people that have or are at risk of having high blood cholesterol levels using television and magazine advertising.

The television market is segmented into age groups and a media agency places advertising in times for the shows that people in these groupings will be watching.

National Foods also uses tactical advertisements in magazines which target the relevant people. The magazine titles selected below target people who have an interest in health. People who have specific health concerns such as high cholesterol levels and that are also taking a proactive approach to managing their health are more likely to purchase these magazines.

Healthy Food Guide and Weight Watchers – People who read these magazines are likely to be managing health concerns through diet and being overweight increases the chances of having high cholesterol.

Men's Health – Men who read this magazine are interested in improving their health and fitness and take a proactive approach to managing their health.

Prevention – This magazine provides information on healthy living and lifestyle to prevent illness.

Diabetic Living – People with diabetes on average have higher levels of LDL cholesterol than people without diabetes.

National Foods provides information to health care professionals to make them aware of the product and the benefits so they can recommend it to any of their patients that it would be suitable for.

2.4.5 Cost/Benefit Analysis

2.4.5.1 Industry

87.4% of general milk sales are in pack sizes greater than 1 litre, while only 12% of sales are for 1 litre packs [National Foods calculation based in part on data reported by Nielsen through its ScanTrack service for the Milk Category, fresh white milk segment for the 52-week period ending April 03, 2011, for the Australian total grocery market (Copyright © 2011, Nielsen)].

There is a substantial opportunity for the industry to increase sales of milks enriched with phytosterol (or its equivalents) if the package size restriction is removed. There are environmental advantages due to increased efficiency provided by supply to the market in larger packs.

Alignment with regulations for products on the market in Europe and the USA will be improved and explanation to consumers about the reasons for the pack size limitation will not be required.

There will be some costs associated with launching new products, packaging and factory trials. Industry will be disadvantaged as it would be unable to take advantage of market opportunities to develop and sell these products, if the restriction is not removed. National Foods would also have incurred a cost in research and development.

2.4.5.2 Government

There would be no immediate impact on government. Governments may benefit in terms of overall health expenditure from lower blood cholesterol levels in the community associated with the increased consumption of plant sterols.

There are no benefits to the Government in maintaining a restriction on package size as there may be a health benefit for consumers.

There are no perceived additional costs on jurisdictions that enforce the food regulations as this Application requests the removal of a regulation which restricts packaging size. The proposed change to the regulation would be more closely aligned to products without packaging restrictions such as plant sterol enriched edible oil spreads.

2.4.5.3 Consumers

Consumers will benefit from the availability of larger pack sizes of milk enriched with phytosterols (or their equivalents) as demonstrated by requests received for a more convenient shopping alternative. Consumers are requesting larger pack sizes as 1 litre and smaller packs account for only 12.6% of the total milk market. Between July 2010 and April 2011, 14.6% of consumer enquiries and feedback related to requests for a larger pack size for phytosterol enriched milk (consumer enquiries to National Foods Consumer Enquiry Centre).

Consumers clearly do not understand why they are unable to buy larger than 1 litre packs of this product or pay for and transport two or three containers. Many consumers cannot easily find the product (consumer enquiries to National Foods Consumer Enquiry Centre). The current restriction on pack sizes to 1 litre or less is quite difficult for the manufacturer to explain to customers without causing some alarm.

A further benefit to the consumer will be a price reduction in cost per litre as demonstrated by the current premiums for phytosterol enriched milks. Consumers of phytosterol enriched milks are currently being forced to purchase more expensive 1 litre containers due to a legislative restriction.

For example, consumers currently pay a 13.7% premium per litre when buying 1 litre of National Foods reduced fat milk compared to the 2 litre pack size.

There is a benefit to consumers from consuming plant sterols which has been shown to lead to reductions in their blood cholesterol levels. There are also environmental benefits associated with less use of packaging for larger pack sizes.

A possible cost, albeit unlikely, is that a bigger package of a food containing added plant sterols may lead to consumption of plant sterol-fortified foods in amounts more than necessary to achieve an effect. However, post-launch monitoring data in Europe by EFSA suggests that consumers do not currently achieve optimal intakes. In addition, there is an advisory statement on the label which serves to inform consumers of the appropriate amount to achieve the intended effect, and that there are no additional health benefits when more than 3g of plant sterols are consumed per day.

Another possible cost is that consumers may be subjected to higher costs if they purchase larger than 1 litre containers of phytosterol enriched milk and use this instead of other milks for general household use. Consumers will be spending less however on larger packs if they are permitted to be sold, than they currently spend for multiple 1 litre packs. Data on milk purchases by consumers of HeartActive phytosterol enriched milk also indicates that they buy mainly other milks with only 20.1% of purchases on milk containing phytosterols [National Foods calculation based in part on data reported by Nielsen through its Nielsen Homescan for the Milk Category, fresh white milk segment for the 52-week period ending May 14, 2011. (Copyright © 2011, Nielsen)].

Furthermore, 81.9% of HeartActive buyers live in households with a medium to high income [National Foods calculation based in part on data reported by Nielsen through its Nielsen Homescan for the Milk Category, fresh white milk segment for the 52-week period ending April 16, 2011 (Copyright © 2011, Nielsen)].

FSANZ concluded that there are no public health and safety risks from consumption of approved plant sterol-fortified products (FSANZ 2nd Review Report A433, A434 and A508).

2.4.6 FSANZ objectives

Section 18 of the FSANZ Act sets out FSANZ's objectives (in descending priority order) in developing food regulatory measures and variations of food regulatory measures as:

- (a) the protection of public health and safety;

This Application is to delete a restriction on package size and does not raise any health and safety concerns.

- (b) the provision of adequate information relating to food to enable consumers to make informed choices; and

This Application provides an advantage to consumer in terms of choice in larger pack sizes. The average consumer does not understand that there is a legislative restriction on pack size for this product in Australia and New Zealand. There are also advantages for the environment in terms of reductions in food packaging and less trips to the supermarket, which may influence consumer choices.

- (c) the prevention of misleading or deceptive conduct.

The regulatory restriction on package size to 1 litre containers for phytosterol enriched milk was imposed without any justification in terms of considering potential misleading or deceptive conduct. As cited earlier, the Final Assessment Report for Application A434 recommended approval of the request to add phytosterols to milk and did not include any restrictions on package sizes. The packaging restrictions were raised in the First Review Report and no justification from the jurisdictions was required.

In developing food regulatory measures and variations of food regulatory measures, FSANZ must also have regard to the following:

- (a) the need for standards to be based on risk analysis using the best available scientific evidence;
- (b) the promotion of consistency between domestic and international food standards;
- (c) the desirability of an efficient and internationally competitive food industry;
- (d) the promotion of fair trading in food; and
- (e) any written policy guidelines formulated by the Ministerial Council.

The scientific evaluations conducted by FSANZ for phytosterol enriched foods conclude that there are no safety concerns. The current restriction on package size to no more than 1 litre is therefore not based on risk analysis using the best available scientific evidence.

This Application proposes to promote greater consistency with both Europe and the USA.

The current restriction to no more than 1 litre for phytosterol enriched milk, forces consumers in Australia and New Zealand to purchase more than 1 container of the product if they wish to obtain enough product to deliver the proposed health benefits for one person for more than two days or for more than one person for one day. This is not a desirable outcome in terms of an efficient and internationally competitive food industry.

The current restriction on package size to no more than 1 litre for milk enriched with phytosterol or its equivalents does not promote fair trading in food.

There are no written policy guidelines formulated by the Ministerial Council that impact on the package sizes for milk enriched with phytosterol or its equivalents.

2.4.7 Applicant's Objectives

The Applicant seeks to market bigger packs of milk enriched with phytosterols (or their equivalents) as requested by customers.

2.4.8 Nutritional implications

As concluded in FSANZ's 2nd Review Report for phytosterol Applications A433, A434 and A508: "Milk is an effective vehicle for delivery of phytosterols, lowering serum cholesterol levels by up to 15%".

In accordance with the Health Claim permitted in the USA, Kroger stores state for their phytosterol enriched products; "Foods containing at least 0.4 grams per serving of plant sterols, eaten twice a day with meals for a daily total intake of at least 0.8 grams, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease."

There are also similar large packs of Healthy Chekd milk and Active Lifestyle Fat Free milk as well as breads and orange juice with CoroWise™ plant sterols on sale in the USA.

Phytosterol enriched milks are required to contain from 3 to 4 g/litre of phytosterol content in Australia and New Zealand. 1 litre of milk contains four serves of 250 mL. Two serves per day of phytosterol enriched milk would therefore supply about 1.5 - 2 g of phytosterols. As stated in the FSANZ Fact Sheet on plant sterols (2010), plant sterols are most effective if we eat two to three grams per day and that this is roughly equivalent to two to three serves of foods containing plant sterols.

2.4.9 Dietary implications

Phytosterols and phytostanols, also referred to as plant sterols and stanols, are common plant and vegetable constituents and are therefore normal constituents of the human diet. Dietary intake of phytosterols ranges from 150-400 mg /day in a typical western diet. Phytosterols and phytostanols, in free or esterified form, are added to foods for their properties to reduce absorption of cholesterol in the gut and thereby lower blood cholesterol levels. It is now generally accepted that sterols and stanols have the same cholesterol lowering efficacy.

The daily doses, considered optimal for the purpose of lowering blood cholesterol levels, are 2-3 g of phytostanols and/or phytosterols, which translates to 3.4-5.2 g in esterified form. This recommended daily dose is typically divided in 1-3 portions of food providing 1.7-5.2 g ester, which equals 1-3 g phytostanol and/or phytosterol equivalents (Chemical and Technical Assessment for the 69th JECFA). The equivalence of phytosterols and phytostanols and their esters was considered by FSANZ in Application A1024.

Advice to consume carotenoid-rich fruit and vegetables is not justified on the grounds that the reduction in serum beta-carotene is not indicative of any nutritional deficiency and is within natural variation (FSANZ 2nd Review Report A433, A434 and A508).

2.4.10 Advantage to the consumer

National Foods has received requests for larger pack sizes of milk enriched with phytosterols (or their equivalents). If there are more than one consumers of the product in a household or if more than two serves are consumed in a day, a 1 litre pack will only last for one day. Such households can purchase more than one pack but it would be more convenient and cost effective to purchase 2 or 3 litre bottles.

2.5 Assessment Procedure

(as required by section 3.1.6 of the Application Handbook)

National Foods proposes to proceed as an unpaid Application with minor complexity.

2.6 Confidential Commercial Information

(as required by section 3.1.7 of the Application Handbook)

No Confidential Commercial Information is contained in this Application.

2.7 Exclusive Capturable Commercial Benefit

(as required by section 3.1.8 of the Application Handbook)

National Foods does not seek to have exclusive use of the larger than 1 litre package size for milk enriched with phytosterols (or their equivalents).

2.8 International and other National Standards

(as per section 3.1.9 of the Application Handbook)

2.8.1 International Standards

There is no Codex Alimentarius Commission Standard for milk as it is not a significant commodity in international trade.

The Commission provides standards for a number of dairy products including Butter, Milkfat Products, Evaporated Milks, Sweetened Condensed Milks, Cheese and Whey Cheese. There is also a Codex General Standard for the Use of Dairy Terms.

2.8.2 National Standards

Table spreads enriched with plant-derived stanols were introduced into the food supply in the mid-1990s in Finland. The use of plant sterol or stanol-based foods expanded into other countries including the United States (USA), Brazil, Switzerland (1999), Australia and New Zealand (2001).

The European Standing Committee for the Food Chain and Animal Health recommended approval for phytosterols to be added to milk type products and salad dressing/spicy sauces, in addition to the existing yellow fat spreads (December, 2003).

Milk type products, yoghurt type products, salad dressings, spicy sauces, fermented milk type products, soya drinks and cheese type products containing phytosterols/phytostanols are authorised for placing on the market in the European Community, in addition to the permitted yellow fat spreads (Commission Decision 2004/336, 335, 334, 333/EC).

The UK Food Standards Agency approved an application from Unilever seeking approval for the use of phytosterol-esters (equivalent to 1g of free phytosterols per serving) in milk and yoghurt type products as provided for by EC Directive 335.

In the USA, a number of vegetable oil sterol esters, that meet appropriate food-grade specifications and are produced by current good manufacturing practice (21 CFR section

182.1(b)), have been notified under the GRAS system. The US Food and Drug Administration (FDA) have raised no objection to a number of food products (see below) that may contain plant sterol and stanol esters in amounts up to 20%.

The FDA has also issued an interim final rule (Sept 2000, 21 CFR section 101.83 2), which allows manufacturers of products containing added phytosterol and stanol esters to make a health claim (for reducing the risk of coronary heart disease).

In the USA, a number of foods that are allowed to use this interim health claim include sterol esters in spreads and salad dressings, and stanol esters in spreads, salad dressings, snack bars and dietary supplements in soft gel form (FSANZ FAR A433).

The USFDA proposed an extension of the health claim to allow for mixtures of plant sterols, stanols and their esters in December 2010 (CFR Title 21 101).

There do not appear to be any restrictions on package sizes in legislative requirements for phytosterol enriched milks in Asia.

China's food regulations are complex with around ten national government departments that share the responsibility for food safety. There are also numerous provincial and local agencies that monitor local food production and sales. The Chinese Ministry of Health announced a new national dairy standard, altogether 66-items, including 15 product standards, two production standards, and 49 inspection method standards. (http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Dairy%20and%20Products%20Annual_Beijing_China%20-%20Peoples%20Republic%20of_10-22-2010.pdf)

Singapore's Agri-Food and Veterinary Authority is responsible for food regulations.

The Sale of Food Act is 1 of 9 statutes and regulations 93 to 109 cover dairy products (<http://www.ava.gov.sg/>). There is no apparent restriction on packaging for milk products.

Malaysia has a guide to Nutrition Labelling and Claims, with a reference to the addition of sterols, stanols and their esters to milk, without reference to pack sizes (<http://fsis2.moh.gov.my/fosimv2/HOM/frmHOMFARSec.aspx?id=21>).

2.8.2.1 Europe

The following are the relevant Commission decisions under European Community: Regulation (EC) No. 258/97 of the European Parliament and of the Council concerning novel foods and novel food ingredients.

Novel Foods and Novel Food Ingredients Regulations 1997 (S.I. No. 1335 of 1997). - 21 May 1997 [LEX-FAOC019203]

Commission Decision 2000/500/EC on authorizing the placing on the market of 'yellow fat spreads with added phytosterol esters' as a novel food or novel food ingredient under Regulation (EC) 258/97 of the European Parliament and of the Council. - 08 August 2000 [LEX-FAOC020938]

Commission Decision 2004/333/EC authorising the placing on the market of yellow fat spreads, salad dressings, milk type products, fermented milk type products, soya drinks and cheese type products with added phytosterols/phytostanols as novel foods or novel food ingredients under Regulation (EC) No. 258/97 of the European Parliament and of the Council. - 31 March 2004 [LEX-FAOC042394]

Commission Decision 2004/335/EC authorising the placing on the market of milk type products and yoghurt type products with added phytosterol esters as novel food ingredients under Regulation (EC) No. 258/97 of the European Parliament and of the Council. - 31 March 2004 [LEX-FAOC042395]

Commission Decision 2004/845/EC of 12 November 2004 on authorising the placing on the market of milk based beverages with added phytosterols/phytostanols as novel foods or novel food ingredients under Regulation (EC) No 258/97 of the European Parliament and of the Council.

2.8.2.2 United States of America

The United States Code of Federal Regulations (CFR), Title 27, Laws and Regulations under the Federal Alcohol Administration Act contains regulation 101.83, with claims relating to phytosterols in parts (G) and (H) below:

§ 101.83 Health claims: plant sterol/stanol esters and risk of coronary heart disease (CHD), December 2005

(G) The claim specifies the daily dietary intake of plant sterol or stanol esters that is necessary to reduce the risk of CHD and the contribution one serving of the product makes to the specified daily dietary intake level. Daily dietary intake levels of plant sterol and stanol esters that have been associated with reduced risk of are:

(1) 1.3 g or more per day of plant sterol esters.

(2) 3.4 g or more per day of plant stanol esters.

(H) The claim specifies that the daily dietary intake of plant sterol or stanol esters should be consumed in two servings eaten at different times of the day with other foods.

USFDA proposed a new rule in CFR Title 21 101 to broaden the use of the term phytosterols for: Food Labelling; Health Claim; Phytosterols and Risk of Coronary Heart Disease.

FDA is proposing to amend the regulation authorizing a health claim on the relationship between plant sterol esters and plant stanol esters and reduced risk of coronary heart disease (CHD) for use on food labels and in food labelling. The agency is taking this action based on evidence previously considered by the agency, and FDA's own review of data on esterified and non-esterified plant sterols and stanols (collectively, phytosterols) published since the agency first authorized the health claim by regulation.

The term “phytosterols” is used as a collective term for plant sterols and their hydrogenated stanol forms, whether used in the free form or esterified with fatty acids. As discussed in more detail elsewhere in this proposal, phytosterol is a term commonly used by manufacturers and distributors of these substances.

PART 3 REGULATORY IMPACT STATEMENT

(as per section 2.2.9 of the Application Handbook)

There are no regulatory impediments to this requested change to increase the package size for milk enriched with phytosterols (or their equivalents) as any adverse effects on consumers, government and industry are minimal.

3.1 Consumers

Consumers will not be disadvantaged by the proposed change to remove the restriction on pack sizes. FSANZ's assessment clearly shows that this restriction was not imposed due to any health and safety concern, but as an attempt to ensure that efficacy was optimised by restricting the number of servings.

Consumers are currently paying a premium price if they wish to purchase more than one container of product as detailed in the cost/benefit analysis.

3.2 Industry

Industry will be able to increase cost efficiency of sales and as a flow on effect, the health benefit to consumers. The current restriction on pack size could be regarded as an anticompetitive regulatory impediment if anyone wishes to import this product from the USA.

There is a benefit to industry in the more efficient use of packaging for larger containers and for subsequent disposal costs.

3.3 Government

There are minimal impacts on governments due to removing the restriction on pack size.

There are no benefits to the Government in maintaining a restriction on package size as there may be a health benefit for consumers.

There are no perceived additional costs on jurisdictions that enforce the food regulations as this Application requests the removal of a regulation which restricts packaging size.

PART 4 A NON-COMPOSITIONAL CHANGE TO A STANDARDISED FOOD

(as per section 3.6 of the Application Handbook)

The current restriction on the package size is provided by clause 5 (b) of Standard 2.5.1 – Milk.

Milk is a standardised food and for the purposes of meeting the requirements of the Application Handbook in Part 3.6.1, the request for deletion of clause 5 (b) is most appropriately treated as a change to a compositional requirement.

There is however, no actual change to the composition of milk proposed and no foods or food standards would be affected by allowing for the sale of larger package sizes.

There is no anticipated change in the overall nutrient content of milk. The Applicant hopes to increase sales of HeartActive phytosterol enriched milk resulting from the availability of larger pack sizes of the currently permitted product. Increased consumption of phytosterol enriched milk should have a beneficial effect on the diet of consumers who wish to lower their serum cholesterol levels.

4.1 Information on consumer understanding and behaviour

According to the Application Handbook:-

The extent of the impact of a food compositional change on consumer understanding and behaviour will vary depending on:

- (a) the nature of the compositional change; and
- (b) the foods to which it will apply.

Thus the amount of information necessary to address the impact on consumer understanding and behaviour will depend on the level of impact. Consultation with FSANZ may be necessary to examine the expected level of impact.

There is however no proposed compositional change to the product for consumers to understand. The impact on consumer behaviour resulting from a change in packaging size is expected to be minimal. The overall effect of allowing an increase in package size is most likely to be lower serum cholesterol levels being achieved by consumers of the product.

Enquirers about HeartActive phytosterol enriched milk do not understand why they cannot purchase bigger packages. Consumers do not understand that there is a legislative restriction on the package size. Consumers also do not understand why there should be any package size restriction on a product that they are buying to improve their health.

The United Kingdom Food Standards Agency (UKFSA) commissioned consumer research on health claims including a case study on phytosterols. The report concluded that the

relationship between consumers, products and claims is complex and that it is difficult to generalise about the impact on consumer understanding of the claim itself.

4.2 Adverse health or diet impacts on population groups (e.g. age or cultural groups)

There is no increased safety concern associated with consumption of foods currently permitted to contain plant sterols and no ADI has been established for phytosterols (or their equivalents) in Australia and New Zealand. The requested change to packaging is not a compositional change.

As concluded in FSANZ's assessment report for Application A1019: A comprehensive review of the literature does not indicate any population health risk arising from consumption of plant sterol fortified foods.

The USA allows a health claim for phytosterol enriched foods and the product is marketed on the basis of its serum cholesterol lowering effects.

The risk assessment for A1019 concluded that there is likely to be a very small proportion of children (2-3%) aged 2-16 years who consume phytosterol-fortified products. Phytosterol enriched milks are however, targeted specifically to people at risk of high blood cholesterol levels and current data on consumer purchases of milk further supports the conclusion in A1019. There is also a labelling requirement specifying that the product may not be suitable for children under the age of 5 years.

Rural and regional consumers of phytosterol enriched milk will find it more convenient to purchase larger bottles of the product rather than the currently available 1 litre cartons.

There is no public health-based justification for maintaining the restriction on package size for milk enriched with phytosterols (or their equivalents).

4.3 Information related to impact on the food industry

4.3.1 Projected cost to the food industry

The costs associated with providing larger pack sizes of milk enriched with phytosterols (or their equivalents) are minimal. There will be some costs associated with factory trials and new labelling but the packaging systems are already in use for other larger packages of milk products, which are sold in much larger volumes.

The increase in sales volume of phytosterol enriched milk due to a bigger pack size is difficult to predict. Sales of milk in 1 litre containers are 12% of the market, so there is potential for a substantial increase in sales. There are however many milk products currently available for consumers to choose from in the 2 and 3 litre pack sizes with sales greatly

influenced by current supermarket discounting. The availability of a larger pack size is unlikely to have any effects on small businesses.

4.3.2 Impact on international trade

There is no significant international trade in liquid milks and Australia and New Zealand are both major exporters of dairy products. The Applicant is not currently marketing the 1 litre product in New Zealand.

There are unlikely to be any significant effects on imports of milks enriched with phytosterol or its equivalents due to the removal of a package size restriction. The current restriction could be regarded as an anticompetitive regulatory impediment to trade if anyone tried to import a 2 litre product.

The impact on international trade resulting from removal of the packaging restriction in Australia and New Zealand will be minimal.

Alignment with regulations for products on the market in Europe and the USA will also be improved.

REFERENCES

1. Chemical and Technical Assessment
PHYTOSTEROLS, PHYTOSTANOLS AND THEIR ESTERS. Prepared by Richard Cantrill, Ph.D., reviewed by Yoko Kawamura, Ph.D., for the 69th JECFA 2009. (accessed 24 April 2011)
http://www.fao.org/ag/agn/agns/jecfa/cta/69/Phytosterols_CTA_69.pdf
2. European Community: Regulation (EC) No. 258/97 of the European Parliament and of the Council concerning novel foods and novel food ingredients. (accessed 24 April 2011). <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1997R0258:20090120:EN:PDF>
Date of text: 27 January 1997. Source: CELEX-EUR Official Journal L 43, 14 February 1997, pp. 1-7.
3. European Food Safety Authority consumer research report on phytosterols, February 2008, (accessed 24 April 2011).
http://www.efsa.europa.eu/en/scdocs/doc/datex_report_ej133_phytosterols_en.pdf
4. FSANZ Fact Sheet; Plant sterols January 2010
<http://www.foodstandards.gov.au/scienceandeducation/factsheets/factsheets2010/plantsterolsjanuary24705.cfm>
5. FSANZ Final Assessment Report for A433
http://www.foodstandards.gov.au/srcfiles/A433_Phytosterols_in_cereals_FAR_FINAL.pdf
6. FSANZ Final Assessment Report for A434
http://www.foodstandards.gov.au/srcfiles/A434_Phytosterols_in_low_fat_milk_FAR_FINAL.pdf
7. FSANZ Approval Report for A1019
<http://www.foodstandards.gov.au/srcfiles/A1019%20Phytosterol%20esters%20in%20lower%20fat%20cheese%20AppR.pdf>
8. FSANZ Approval Report for A1024
<http://www.foodstandards.gov.au/foodstandards/applications/applicationa1024equi4316.cfm>

9. FSANZ's 1st review report (Application A433 Phytosterol Esters Derived from Vegetable Oils in Breakfast Cereals; Application A434 Phytosterol Esters Derived from Vegetable Oils in Low-Fat Milk & Yoghurt Application A508 Phytosterols Derived from Tall Oils as Ingredients in Low-Fat Milk).
http://www.foodstandards.gov.au/srcfiles/A433,%20A434,%20A508%20Phytosterols%20FRR_FINAL.pdf
10. FSANZ's 2nd review report (Application A433 Phytosterol Esters Derived from Vegetable Oils in Breakfast Cereals; Application A434 Phytosterol Esters Derived from Vegetable Oils in Low-Fat Milk & Yoghurt Application A508 Phytosterols Derived from Tall Oils as Ingredients in Low-Fat Milk).
<http://www.foodstandards.gov.au/srcfiles/A434%20Phytosterols%20in%20low%20fat%20milk%20SRR%20FINAL.pdf>
11. Kroger stores website accessed 4 June 2010 (<http://www.corowise.com/wheretobuy/>).
12. National Heart Foundation, Position statement on phytosterol/stanol enriched foods (2007) updated December 2009 (accessed 4 June 2010)
http://www.heartfoundation.org.au/SiteCollectionDocuments/HW_FS_SterolsStanols_PS_FINAL_LR.pdf
13. United Kingdom Food Standards Agency Report on phytosterols consumption (accessed 24 April 2011).
http://foodbase.org.uk/admintools/reportdocuments/210-1-363_G03021.pdf
14. USA Regulations (accessed 24 April 2011). 21 CFR Ch. I (4–1–09 Edition) § 101.83 Health claims: plant sterol/ stanol esters and risk of coronary heart disease (CHD).
http://edocket.access.gpo.gov/cfr_2009/aprqr/pdf/21cfr101.83.pdf
15. USFDA 21 CFR 101 Food Labeling; Health Claim; Phytosterols and Risk of Coronary Heart Disease (accessed 24 April 2011)
<http://federalregister.regstoday.com/ViewSummary.aspx?ds=20101208&ct=CITA&cv=21%20CFR%20101%20-%20FOOD%20LABELING>

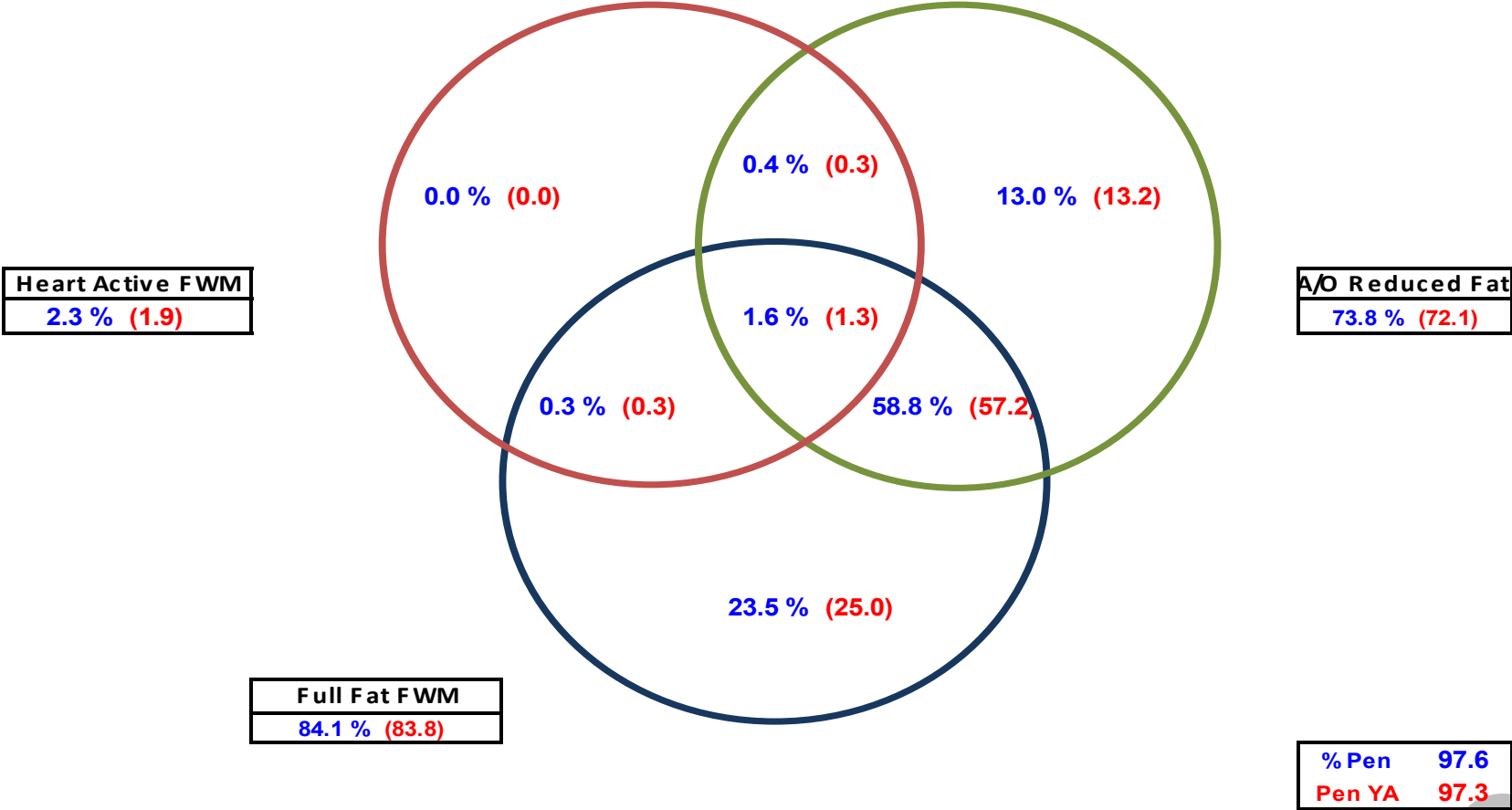
HeartActive – National Foods Milk

The Nielsen logo is located in the bottom right corner of the slide. It consists of the word "nielsen" in a lowercase, sans-serif font, with a series of dots underneath it. The logo is white and is set against a blue background that features a white curved line at the bottom.

nielsen
.....

100% of Heart Active buyers purchasing either other Reduced Fat/Full Fat or both. There is high interaction between Heart Active buyers and Other Reduced Fat/ Full fat vs. YA

AUS | MAT to 16/04/2011 Vs YA
(100% Penetration-Heart Active FWM,A/O Reduced Fat & Full Fat FWM)

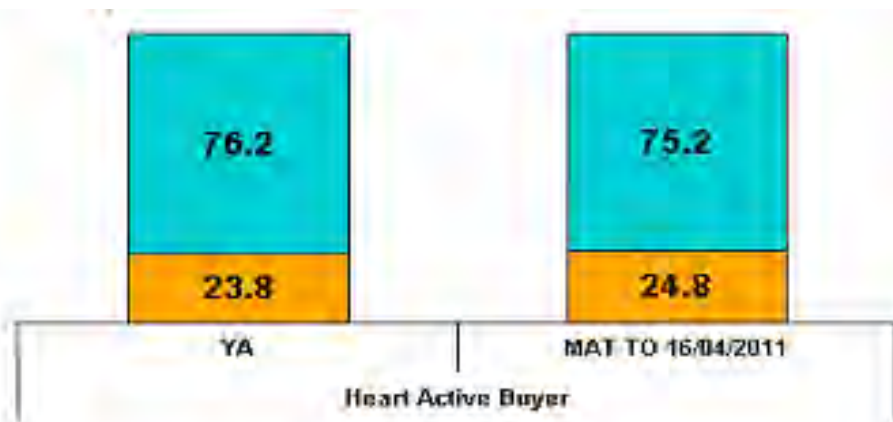


Source- Nielsen Australia Home scan : Issue # 472331,472335

Majority of Households buying Heart Active has NO children and more Households with children are buying Heart Active

Demographic Distribution of Buyers For Period MAT TO 16/04/2011 vs. YA | AUS

Distribution of buyers



Distribution of volume

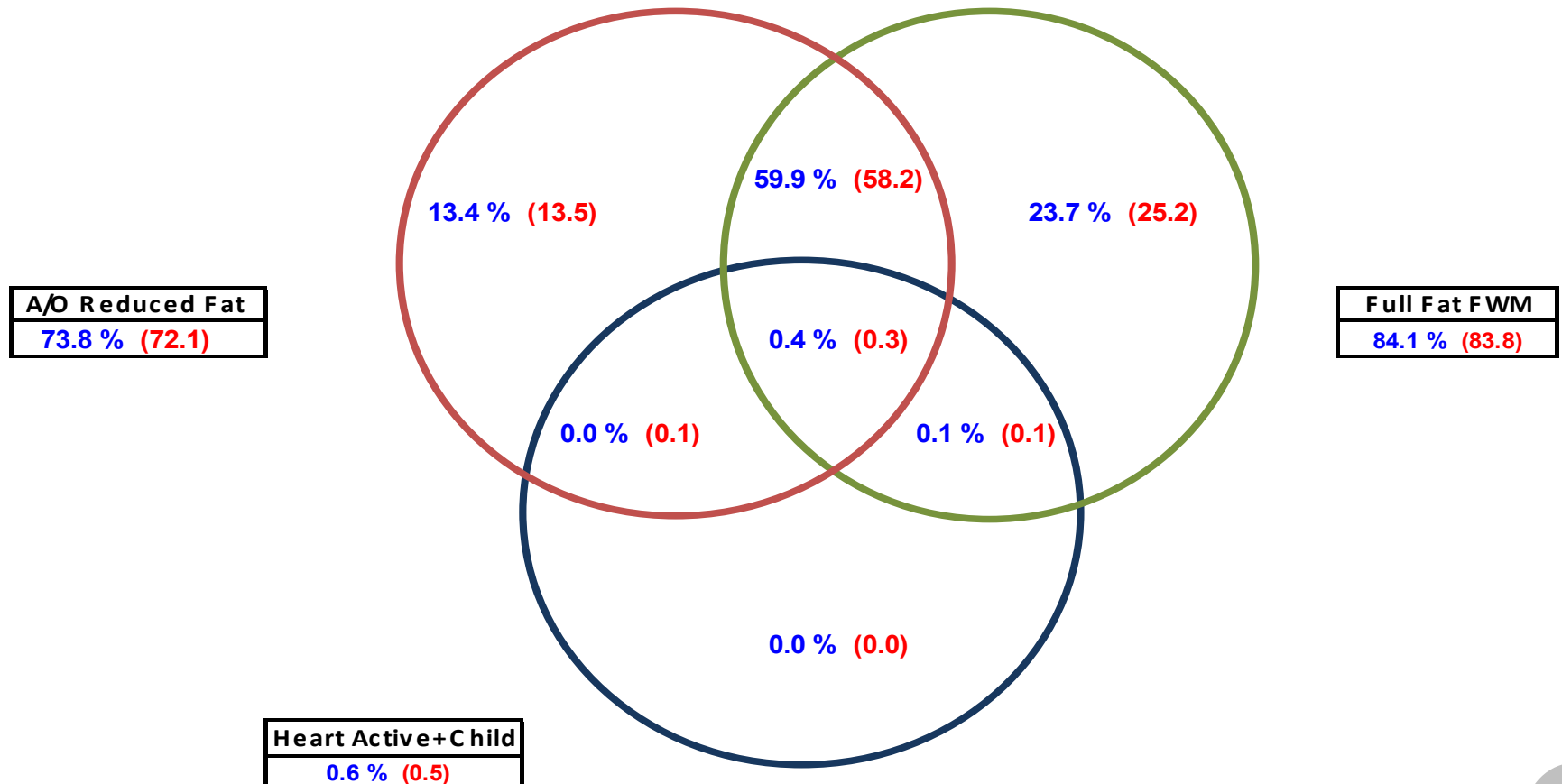


- Presence of Children - No
- Presence of Children - Yes

	Total Panel
HHs with Children	30%
HHs without children	70%

More Households purchasing Full Fat & Other Reduced Fat are now also buying Heart Active

AUS | MAT to 16/04/2011 Vs YA
(100% Penetration-A/O Reduced Fat , Full Fat FWM & Heart Active+Child)



Source- Nielsen Australia Home scan : Issue # 472436,472444

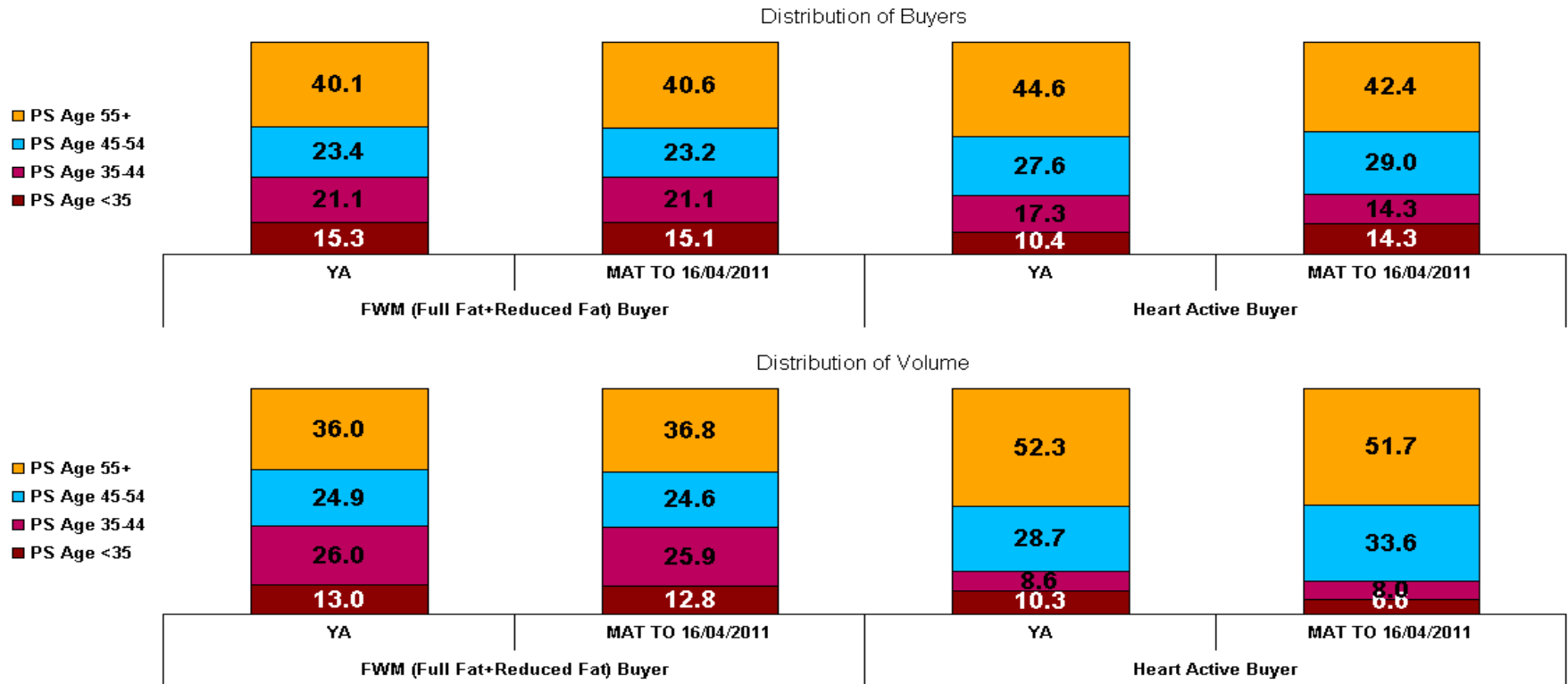
Please use data with discretion

% Pen 97.6
Pen YA 97.3

4

Demographic Distribution of Buyers

For Period MAT TO 16/04/2011 vs. YA | AUS

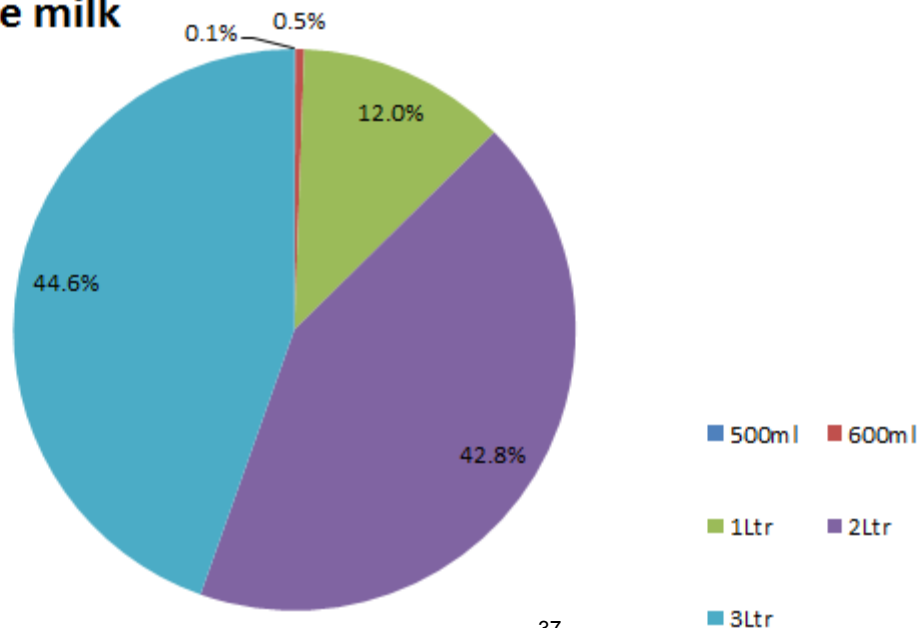


Source: ACNielsen | Homescan® (Australia) - Issue # 472456

Milk container sizes

T. Fresh White Milk	MAT To 03/04/2011	% share	Total	% share
Total 250ml	13.6	0.002%		
Total 300ml	430.0	0.049%		
Total 375ml	14.3	0.002%		
Total 500ml	37.2	0.004%		
Total 600ml	4,407.0	0.500%	500ml	0.1%
Total 1Ltr	106,051.9	12.029%	600ml	0.5%
Total 1.1Ltr	254.7	0.029%	1Ltr	12.0%
Total 2Ltr	377,551.0	42.823%	2Ltr	42.8%
Total 3Ltr	392,823.1	44.556%	3Ltr	44.6%
Total 4Ltr	61.7	0.007%		
	881,644.4			100.0%

Fresh White milk



Price premium calculation

	MAT To 05/06/2011
	Bench Price per Unit (\$)
Dary Farmrs Hrt Actv 99% F/Fr Mlk 1L Ctn	2.80
Pura Heart Active 99% F/Free Milk 1L Ctn	2.80
average price full fat per lite (1Ltr & 2Lrt pack size)	2.10
price premium HeartActive compared to full fat milks	33.3%
average price reduced fat per lite (1Ltr & 2Lrt pack size)	2.00
price premium HeartActive compared to reduced fat	40.0%

NFL price premium reduced fat milk

Reduced fat average price 1Ltr	2.4
Reduced fat average price 2Ltr	2.11
+% 2Ltr vs 1Ltr	13.7%

Appendix 2 - Roy Morgan Data

Job: MILK AND CONVENIENCE STORES: APR09-MAR11

Title:

Filter: All cases, Layer: All cases, Ranking: No ranking, Population In '000s

Page 1

MILK AND CONVENIENCE STORES: APR09-MAR11									
TOTAL	Total HeartActive bought in past 12 months						Total HeartActive consumer last 7 days		
	wc	v%	ix	wc	v%	ix	wc	v%	ix
(popn. '000)	18112			125			78		
AGE - summary									
14-17	1126	6.2%	100	4	3.1%	51	2	3.0%	49
18-24	2030	11.2%	100	4	3.0%	27	7	8.4%	75
TOTAL 14-24	3157	17.4%	100	8	6.2%	36	9	11.4%	66
25-34	3091	17.1%	100	11	8.8%	52	4	4.9%	29
35-49	4842	26.7%	100	33	25.9%	97	20	26.0%	97
TOTAL 50 and Over	7022	38.8%	100	74	59.0%	152	45	57.6%	149
50-64	4002	22.1%	100	50	39.7%	180	28	35.9%	163
65 and Over	3020	16.7%	100	24	19.3%	116	17	21.7%	130
TOTAL 18 and Over	16986	93.8%	100	121	96.9%	103	76	97.0%	103
TOTAL HOUSEHOLD INCOME									
Under \$15000 (10)	591	3.3%	100	3	2.3%	71	2	2.7%	81
\$15000 to \$19999 (17.5)	569	3.1%	100	5	3.9%	125	3	3.7%	119
\$20000 to \$24999 (22.5)	677	3.7%	100	4	3.2%	85	2	3.0%	81
\$25000 to \$29999 (27.5)	790	4.4%	100	6	4.6%	106	5	6.7%	153
\$30000 to \$34999 (32.5)	612	3.4%	100	3	2.1%	61	2	3.1%	90
\$35000 to \$39999 (37.5)	564	3.1%	100	3	2.5%	82	3	3.6%	114
\$40000 to \$49999 (45)	1106	6.1%	100	10	7.8%	128	5	6.2%	101
\$50000 to \$59999 (55)	992	5.5%	100	7	5.4%	99	6	7.4%	135
\$60000 to \$69999 (65)	907	5.0%	100	5	4.2%	84	4	5.3%	105
\$70000 to \$79999 (75)	932	5.1%	100	7	5.4%	105	3	4.0%	78
\$80000 to \$89999 (85)	891	4.9%	100	3	2.5%	51	3	4.2%	86
\$90000 to \$99999 (95)	763	4.2%	100	4	3.3%	77	3	4.0%	95
\$100000 to \$109999 (105)	784	4.3%	100	5	4.2%	96	2	2.1%	49
\$110000 to \$119999 (115)	610	3.4%	100	3	2.0%	60	1	1.7%	50
\$120000 to \$129999 (125)	587	3.2%	100	6	4.9%	151	4	4.8%	149
\$130000 to \$149999 (140)	690	3.8%	100	7	5.5%	145	5	6.9%	181
\$150000 to \$199999 (175)	1005	5.6%	100	7	5.3%	95	5	6.1%	109
\$200000 to \$249999 (225)	434	2.4%	100	6	4.7%	195	2	3.1%	128
\$250000 or More (280)	397	2.2%	100	7	5.4%	248	2	3.0%	137
No Answer	4212	23.3%	100	26	20.7%	89	15	18.6%	80
Mean	85.06			99.20			88.67		
CHILDREN UNDER 16 IN HOUSEHOLD - NUMBER									
No Children in HH	11664	64.4%	100	96	76.9%	119	64	82.0%	127
1 Child in HH	2693	14.9%	100	13	10.7%	72	8	9.9%	67
2 Children in HH	2527	14.0%	100	9	7.3%	52	4	5.5%	39
3+ Children in HH	1228	6.8%	100	6	5.1%	75	2	2.6%	38
TOTAL with Children U16 in HH	6448	35.6%	100	29	23.1%	65	14	18.0%	50
LIFE-CYCLE OF RESPONDENT									
Single 14-34 no Children	3664	20.2%	100	10	8.1%	40	10	12.7%	63
Single 14-34 Children	284	1.6%	100	1	0.5%	30	-		
Married 14-34 no Children	974	5.4%	100	3	2.7%	49	3	3.7%	69
Married 14-34 Children	1326	7.3%	100	5	3.8%	52	-		
Married 35+ Children	3002	16.6%	100	17	13.3%	80	10	12.7%	76
Married 35+ no Children	5888	32.5%	100	62	49.8%	153	37	47.5%	146
Single 35+ Children	394	2.2%	100	2	1.2%	57	1	0.8%	38
Single 35+ no Children	2581	14.2%	100	26	20.6%	145	18	22.6%	158
HEALTH AND FITNESS - AGREE									
I'm concerned about my cholesterol level	6831	37.7%	100	75	59.5%	158	53	67.0%	178
Roy Morgan Research Pty. Ltd., Melbourne, Australia									

Appendix 3 – Mintel – Milk with plant sterols global sales

Summary

Count of Record ID		Column Labels														
Row Labels		Australia	China	Denmark	Finland	Ireland	Malaysia	Netherlands	Singapore	Spain	Sweden	Taiwan	Turkey	UK	USA	Total
New Packaging		1						1	1	1	1			1	2	10
250		1														1
500													1			1
1000								1		1						3
1200							2									2
1890															1	1
1892.71									1						1	1
New Product		3	1	1	2	1	2	1	1	1	1	1		1	3	16
250		1														1
750														1		1
1000		2		1	2	1			1		1					8
1200							1									1
1300							1									1
1890															1	1
1892.71															2	2
New Variety/Range Extension		1														1
200							2					1		3		7
290							1									1
1000															2	4
Total		4	2	1	2	1	7	1	2	1	1	1	1	4	5	33

Details

1. Record: 1517466, Date: 28 Mar 2011

Fat Free Milk, White Milk, 1890ml, Chilled
Smart Balance Heart Right, GFA Brands, USA

Description: Smart Balance Heart Right Fat Free Milk has been repackaged and is now available in a newly designed recyclable half gallon pack. This kosher certified product is enriched with omega-3 fatty acids to support a healthy heart and natural plant sterols to help support healthy cholesterol levels. This product is said to contain 25% more calcium and 25% more protein than whole milk and to be a good source of potassium. The manufacturer claims to use milk from cows not treated with the growth hormone rBST.

Claims: Vitamin/Mineral Fortified, Stanols/Sterols, Hormone Free, Kosher, Ethical - Environmentally Friendly Package, Low/No/Reduced Fat, High Protein, Functional - Cardiovascular

Nutrition Information: Per 240ml serving (8 servings per pack): Calories 110kcal (of which Calories from fat 10kcal), Total fat 1g (2% DV) (of which Saturated Fat 0g (0% DV), Trans Fat 0g, Polyunsaturated fat 0g, Monounsaturated fat 0g), Cholesterol 5mg (2% DV), Sodium 150mg (6% DV), Potassium 480mg (14% DV), Total carbohydrates 14g (5% DV), Sugars 14g, Protein 10g (20% DV), Vitamin A (10% DV), Calcium (35% DV), Vitamin D (25% DV)

2. Record: 1474518, Date: 13 Jan 2011

Fat Free Milk, White Milk, 1892.71ml, Chilled
Smart Balance Heart Right, GFA Brands, USA

Description: Smart Balance Heart Right Fat Free Milk has been repackaged in a newly designed half gallon recyclable carton. The milk contains a unique blend of nutrients to help support a healthy heart. It provides a heart healthy blend of omega-3s, vitamin E and natural plant sterols, and contains 25% more protein and calcium than whole milk. The ultra pasteurized product is enriched with vitamins A and D, and certified kosher. It is suitable for consumption as part of the Bestlife diet, and does not contain milk from cows treated with rBST.

Claims: Vitamin/Mineral Fortified, Stanols/Sterols, Hormone Free, Kosher, Ethical - Environmentally Friendly Package, Low/No/Reduced Fat, High Protein, Functional - Cardiovascular

Nutrition Information: Per 240ml serving (8 servings per pack): Calories 110kcal (of which Calories from fat 10kcal), Total fat 1g (2% DV) (of which Saturated Fat 0g (0% DV), Trans Fat 0g, Polyunsaturated fat 0g, Monounsaturated fat 0g), Cholesterol 5mg (2% DV), Sodium 150mg (6% DV), Total carbohydrates 14g (5% DV) (of which Sugars 14g), Protein 10g (20% DV), Vitamin A (10% DV), Calcium (35% DV), Vitamin D (25% DV), Vitamin E (20% DV)

3. Record: 1460587, Date: 10 Jan 2011

Milk with Plant Sterols and Dietary Fiber, White Milk, 250ml, Shelf stable
Mengniu / Mönmilk Milk Deluxe, Inner Mongolia Mengniu Dairy Group, China

Description: Mengniu / Mönmilk Milk Deluxe Milk with Plant Sterols and Dietary Fiber has been repackaged and is now available in a multipack containing 12 x 250ml packs. This milk is said to aid in good health.

Claims: Stanols/Sterols

Nutrition Information: Per 100g: Energy 290kJ (3% RDA), Protein 3.3g (6% RDA), Fat 3.8g (6% RDA), Carbohydrate 5g (2% RDA), Sodium 65mg (3% RDA)

4. Record: 1437428, Date: 08 Dec 2010

Milk, White Milk, 1000ml, Chilled
Marigold HL Plant Sterol Plus, Malaysia Dairy Industries, Singapore

Description: Marigold HL Plant Sterol Plus Milk is intended exclusively for people who want to lower their blood cholesterol level. It has high calcium, high protein, low fat, low lactose and with 9 vitamins. According to the manufacturer, Marigold HL Plant Sterol Plus is part of a balanced and varied diet, including regular consumption of fruit and vegetables to help maintain carotenoid levels and has shown lower blood cholesterol. The product is halal certified and retails in a 1L pack.

Claims: Low/No/Reduced Lactose, Vitamin/Mineral Fortified, Low/No/Reduced Allergen, Low/No/Reduced Cholesterol, High Protein, Low/No/Reduced Fat, Halal, Added Calcium, Stanols/Sterols

Nutrition Information: Per 200ml serving (5 servings per pack): Energy 420kJ/100kcal, Protein 10g, Total fat 2g (of which Saturated Fat 1.4g), Cholesterol 8mg, Carbohydrate 10.6g, Lactose 2.4g, Dietary Fiber 0g, Sodium 152mg, Calcium 300mg, Vitamin A 375mcg, Thiamine 1mg, Pyridoxine 2mg, Vitamin C 30mg, Vitamin D3 2.5mcg, Vitamin E 6mg, Vitamin K1 27mcg, Niacin 11mg, Pantothenic acid 7mg, Plant sterol esters 0.65g

5. Record: 1388331, Date: 16 Sep 2010

Milk with Plant Sterols and Dietary Fiber, White Milk, 250ml, Shelf stable
Mengniu / Mönmilk Milk Deluxe, Inner Mongolia Mengniu Dairy Group, China

Description: Mengniu / Mönmilk Milk Deluxe Milk with Plant Sterols and Dietary Fiber is sourced from the world-recognized good quality dairy base. This product retails in a multipack containing 12 x 250ml cartons.

Claims: Stanols/Sterols

Nutrition Information: Per 100g: Energy 290kJ (3% RDA), Protein 3.3g (6% RDA), Fat 3.8g (6% RDA), Carbohydrate 5g (2% RDA), Sodium 65mg (3% RDA)

6. Record: 1280919, Date: 20 Apr 2010

Skimmed Milk Drink with Added Plant Sterols, White Milk, 1000ml, Chilled
Becel Pro-Activ, Unilever, Netherlands

Description: Becel Pro-Activ Magere Melkdrank met Toegevoegd Plantensterol (Skimmed Milk Drink with Added Plant Sterols) has been repackaged in a newly designed 1L recyclable carton. It is said to reduce active cholesterol, and has been approved by the Nederlandse Harstichting (Dutch Heart Foundation). The product contains plant sterols, scientifically proven to actively lower LDL cholesterol levels in the bloodstream. It features the Ik Kies Bewust logo, indicating a healthy food choice that is lower in sugar, sodium and saturated fat. The pasteurised drink is suitable for vegetarians.

Claims: Stanols/Sterols, Ethical - Environmentally Friendly Package, Low/No/Reduced Sugar, Low/No/Reduced Sodium, Vegetarian, Functional - Cardiovascular

Nutrition Information: Per 250ml serving (4 servings per pack): Energy 380kJ/90kcal, Protein 8g, Carbohydrate 13g (of which Sugars 13g), Fat 0.3g (of which Saturated Fat 0.3g), Fibres <0.1g, Calcium 300mg (38% ADH), Sodium 0.15g

7. Record: 1254544, Date: 09 Feb 2010

Milk Powder, White Milk, 1200g, Shelf stable
Nestlé Nesvita Omega Plus, Jarsa Harrisons, Malaysia

Description: Nestlé Nesvita Omega Plus Milk Powder is now available in a newly designed 1.2kg pack. The product is formulated with ActiCol plant sterols and omega 3 and 6 essential fatty acids, which help lower cholesterol level. This high in calcium milk powder is halal certified and contains a reduced fat content.

Claims: Halal, Stanols/Sterols, Low/No/Reduced Fat, Functional - Cardiovascular

Nutrition Information: Per 31g serving (38 servings per pack): Energy 508kJ/122kcal, Fat 2.9g (of which Monounsaturated fat 0.9g, Polyunsaturated fat 0.7g, Saturated Fat 0.5g, Trans Fat 0.1g), Linoleic Acid 0.6g, Alpha-Linolenic Acid 106mg, Protein 6.2g, Carbohydrate 17.7g, Sodium 105mg, Potassium 394mg, Calcium

481mg, Vitamin A 465 IU/UI, Vitamin D 68 IU/UI, Vitamin E 8.7 IU/UI, Vitamin C 23mg, Vitamin B1 0.1mg, Niacin 2mg, Vitamin B6 0.1mg, Folic acid 149µg, Biotin 12.4µg, Plant Sterol 0.5g

8. Record: 1236255, Date: 23 Jan 2010

Milk, White Milk, 1000ml, Chilled

Dairy Farmers HeartActive, National Foods, Australia

Description: Dairy Farmers Heart Active Milk is 99% fat-free and is enriched with natural plant sterols, which can lower cholesterol by up to 15%. Plant sterols work to lower the amount of cholesterol the body absorbs, and according to the manufacturer, benefits can occur in just three weeks. The product is retailed in a 1L recyclable carton.

Claims: Stanols/Sterols, Ethical - Environmentally Friendly Package, Low/No/Reduced Fat, Time/Speed, Functional - Cardiovascular

Nutrition Information: Per 250ml serving (4 servings per pack): Energy 435kJ (5% RDA)/104kcal (5% RDA), Protein 8.3g (17% RDA), Total fat 2.5g (4% RDA) (of which Saturated Fat 1.2g (5% RDA), Trans Fat <0.1g, Polyunsaturated fat 0.5g, Monounsaturated fat 0.5g), Plant Sterols 0.8g, Total carbohydrates 12g (4% RDA) (of which Sugars 12g (13% RDA)), Sodium 113mg (5% RDA), Calcium 308mg (38% RDA)

9. Record: 1179381, Date: 23 Sep 2009

Lactose-Free Fat-Free Milk, White Milk, 1892.71ml, Chilled

Smart Balance, GFA Brands, USA

Description: Smart Balance Lactose-Free Fat-Free Milk is enriched with omega-3 and vitamin E, which are claimed to help maintain a healthy heart, and contains 20% more calcium and protein than whole milk. It also contains 0% saturated fat, is low in cholesterol, and is free from added hormones and antibiotics. This certified kosher product features rich creamy flavor and retails in a one half gallon recyclable carton. Three other varieties are available: 1% Low Fat Milk with HeartRight, which is enriched with 1% plant sterols; 1% Low Fat Milk, with omega-3 and vitamin E; and Fat-Free Milk, with omega-3 and vitamin E.

Claims: Low/No/Reduced Lactose, No Additives/Preservatives, Vitamin/Mineral Fortified, Added Calcium, Low/No/Reduced Cholesterol, Hormone Free, Ethical - Environmentally Friendly Package, Kosher, Low/No/Reduced Fat, High Protein, Low/No/Reduced Allergen, Stanols/

Nutrition Information: Per 240ml serving (8 servings per pack): Energy 110kcal, Total fat 1.5g (2% DV) (of which Saturated Fat 0g (0% DV), Trans Fat 0g, Polyunsaturated fat 0g, Monounsaturated fat 0g), Cholesterol 5mg (2% DV), Sodium 160mg (7% DV), Total carbohydrates 14g (5% DV) (of which Sugars 14g), Protein 10g (20% DV), Vitamin A (10% DV), Calcium (35% DV), Vitamin D (25% DV), Vitamin E (170% DV)

10. Record: 1080792, Date: 24 Apr 2009

Milk, White Milk, 1000ml, Shelf stable

Nestlé Nesvita Omega Plus, Nestlé, Malaysia

Description: Nestlé Nesvita Omega Plus Milk contains Acticol with added plant sterols, which are claimed to help lower cholesterol. This product is high in calcium and contains omega 3 and 6. This fat reduced milk is claimed to contain 45% less fat than ordinary full cream milk. It is halal certified and is retailed in a 1L new design pack.

Claims: Halal, Vitamin/Mineral Fortified, Stanols/Sterols, Low/No/Reduced Fat, Functional - Cardiovascular

Nutrition Information: Per 250ml serving: Energy 490kJ/117kcal, Total fat 4g (of which Monounsaturated fat 1g, Polyunsaturated fat 0.8g, Saturated fat 0.8g, Trans fat 0g), Linoleic acid 0.53g, Alpha Linolenic Acid 75mg, Protein 7.8g, Carbohydrate 12.5g, Calcium 450mg, Vitamin A 1,735 IU/UI, Vitamin D 60 IU/UI, Vitamin E 6.8 IU/UI, Vitamin C 22.5mg, Vitamin B2 0.4mg, Folic acid 123µg, Vitamin B12 0.5µg, Iodine 48µg, Plant Sterol 240mg

11. Record: 1051053, Date: 23 Mar 2009

Milk Powder, White Milk, 1200g, Shelf stable
Nestlé Nesvita Omega Plus, Nestlé, Malaysia

Description: Nestlé Nesvita Omega Plus Milk Powder have been repackaged in a newly designed 1.2kg pack. The milk powder features ActiCol plant sterols and omega 3 and 6 essential fatty acids, which help lower cholesterol level. This halal certified product contains less fat and high in calcium.

Claims: Halal, Stanols/Sterols, Low/No/Reduced Fat, Functional - Cardiovascular

Nutrition Information: Per 31g serving (38 servings per pack): Energy 508kJ/122kcal, Total fat 2.9g (of which Monounsaturated fat 0.9g, Polyunsaturated fat 0.7g, Saturated Fatty Acids 0.5g, Trans fat 0.05g), Linoleic acid 0.6g, Alpha Linoleic Acid 106mg, Protein 8.4g, Carbohydrate 15.5g, Sodium 119mg, Potassium 394mg, Calcium 496mg, Vitamin A 465 IU/UI, Vitamin D 62 IU/UI, Vitamin E 7 IU/UI, Vitamin C 23mg, Vitamin B1 0.1mg, Vitamin B2 0.4mg, Niacin 1.5mg, Vitamin B6 0.2mg, Folic acid 118µg, Vitamin B12 0.8µg, Plant Sterol 0.6g

12. Record: 922251, Date: 02 Jun 2008

Adult Milk Powder, White Milk, 0, Shelf stable
Nestlé Omega Plus, Nestlé, Singapore

Description: Nestlé Omega Plus Adult Milk Powder is now available in a pack of 15 stick packs. Its formula features ActiCol plant sterols and omega 3 and 6 essential fatty acids, which are said to lower blood cholesterol level. Two glasses of this drink provide 1.2g plant sterols. This product is fortified with calcium to help strengthen bones and contains 60% less fat than ordinary full cream milk. The pack contains the equivalent of 3.75L of milk and features the Singapore Heart Foundation logo.

Claims: Vitamin/Mineral Fortified, Added Calcium, Stanols/Sterols, Low/No/Reduced Fat, Functional - Bone Health

Nutrition Information: Per 100g: energy 1,640kJ/393kcal, 9.4g total fat of which 3.46g monounsaturated and 2.74g polyunsaturates and 2.31g saturated, 2.0g linoleic acid, 343mg alpha-linolenic acid, 27.0g protein, 50g carbohydrate, 385mg sodium, 1270mg potassium, 1600mg calcium, 0g dietary fibre, 4.4mg cholesterol, 1,500/450 I.U./µgRE vitamin A, 200/5.0 I.U./µg vitamin D, 22.5/15 I.U./µgTE vitamin E, 75mg vitamin C, 0.40mg vitamin B1, 1.40mg vitamin B2, 0.65mg vitamin B6, 4.8mg niacin, 380µg folic acid, 2.50µg vitamin B12, 1.9g plant sterol

13. Record: 909908, Date: 07 May 2008

Skimmed Milk, White Milk, 500ml, Shelf stable
Ülker Kalbim Benecol, Ülker, Turkey

Description: Ülker Kalbim Benecol Skimmed Milk is claimed to help reduce cholesterol with plant esters. This product has been re-packaged and is available in a 500ml recyclable pack.

Claims: Stanols/Sterols, Ethical - Environmentally Friendly Package

Nutrition Information: Per 100ml, energy 137.52kJ/32.90 kcal, 3.10g protein, 0.15g fat, 4.80g carbohydrates, 0.40g plant stanol

14. Record: 844121, Date: 28 Jan 2008

Reduced Fat Milk Powder, White Milk, 1200g, Shelf stable
Nestlé Omega Plus, Nestlé, Malaysia

Description: Nestlé Omega Plus Reduced Fat Milk Powder is now available in a new 1.2kg pack. It contains ActiCol with added plant sterols which helps lower cholesterol. It also contains omega 3 and 6, is high in calcium and low in fat. This product is halal certified and is not suitable for babies.

Claims: Halal, Functional - Other, Stanols/Sterols, Low/No/Reduced Fat

Nutrition Information: Per 100g: Energy 1,640kJ/393kcal, Fat 9.4g, Monounsaturated fat 2.9g, Polyunsaturated fat 2.26g, Saturated Fat 1.27g, Trans Fat 0.16g, Linoleic Acids 2g, Alpha-linoleic Acid 343mg, Protein 27g, Carbohydrate 50g, Moisture 3.5g, Sodium 385mg, Potassium 1,270mg, Calcium 1,600mg, Vitamin A 40µg, Vitamin D 5mcg, Vitamin E 15µg, Vitamin C 75mg, Vitamin B1 0.4mg, Vitamin B2 1.4mg, Niacin 4.8mg, Vitamin B6 0.65mg, Folic acid 380µg, Vitamin B12 2.5µg, Plant Sterol 1.9g

15. Record: 816277, Date: 28 Nov 2007

Powder Milk, White Milk, 200g, Shelf stable
Nestlé Omega Plus, Nestlé, Malaysia

Description: New under the Nestlé Omega Plus brand is a Powder Milk that is high calcium and low fat. It contains ActiCol with added plant sterols to help to lower cholesterol and is enriched with omega 3 & 6. This product is halal certified and is available in a 200g pack.

Claims: Vitamin/Mineral Fortified, Stanols/Sterols, Low/No/Reduced Cholesterol, Low/No/Reduced Fat, Halal, Added Calcium

Nutrition Information: Per 100g: energy 1,640kJ/393kcal, 9.4g fat, 2.9g monounsaturated fat, 2.26g polyunsaturated fat, 1.27g saturated fat, 0.16g trans fatty acids, 2.0g linoleic acid, 343mg alpha-linolenic acid, 27.0g protein, 50.0g carbohydrate, 3.5g moisture, 385mg sodium, 1,270mg potassium, 1,680mg calcium, 1,500IU/450mcg RE vitamin A, 200IU/5.0mcg vitamin D, 22.5IU/15mg TE vitamin E, 75mg vitamin C, 0.40mg vitamin B1, 1.40mg vitamin B2, 4.8mg niacin, 0.65mg vitamin B6, 380mcg folic acid, 2.50mcg vitamin B12, 1.9g plant sterol

16. Record: 800733, Date: 25 Oct 2007

Cholesterol Lowering Fat Free Milk, White Milk, 1892.71ml, Chilled
Kroger Active Lifestyle, Kroger, USA

Description: Kroger is launching Cholesterol Lowering Fat Free Milk in a half-gallon size. It will be distributed in Kroger's Active Lifestyle stores. The product contains CoroWise plant sterols, which are available from vegetables, nuts and seeds. Plant sterol compounds are believed to have LDL cholesterol lowering attributes and they can also reduce the chances of developing cardiovascular diseases. It is also fortified with vitamins A & D.

Claims: Vitamin/Mineral Fortified, Stanols/Sterols, Low/No/Reduced Cholesterol, Low/No/Reduced Fat

Nutrition Information: Serving size 8-fl.oz. servings per container 8, calories 90, calories from fat 0, total fat 0g, saturated fat 0g, trans fat 0g, cholesterol <5mg, sodium 125mg, total carbohydrate 13g, dietary fiber 0g, sugars 12g, protein 8g, vitamin A 10%, vitamin C 4%, calcium 30%, iron 0%, vitamin D 25%

17. Record: 755251, Date: 16 Oct 2007

Plant Sterols Milk, White Milk, 290ml, Chilled
Uni-President, Uni-President Enterprises, Taiwan

Description: Uni-President Plant Sterols Milk contains 1.04g plant sterols per bottle, equal to the amount contained in 5.8kg of cauliflower. The plant sterols is only are claimed to help reduce cholesterol levels. An animal study shows that consumption of this product may help lower blood total cholesterol. The product is retailed in a 290ml bottle.

Claims: Stanols/Sterols

Nutrition Information: Per 100ml: energy 52kcal, 2.8g protein, 2.0g fat, 5.8g carbohydrate, 46mg sodium, 1.0g dietary fibre, 100mg calcium, plant sterols 360mg

18. Record: 749035, Date: 02 Aug 2007

Low Fat Milk, White Milk, 1000ml, Shelf stable
Devondale Reduce, Murray Goulburn, Australia

Description: Devondale Reduce Low Fat Milk is pasteurised at an ultra high temperature and packed in a sterile tetra pack so it stays fresh for up to nine months without refrigeration. It is high in calcium and is said to reduce your cholesterol absorption, thanks to its plant sterols ingredient. This milk contains no preservatives and retails in a 1L pack.

Claims: No Additives/Preservatives, Stanols/Sterols, Low/No/Reduced Fat

Nutrition Information: Per 100ml: energy 230kJ, 4.0g protein, 1.4g total fat, of which 0.8g saturated fat, 0.36g monounsaturated fat, 0.2g polyunsaturated fat, 0.04g trans fatty acids, 0.32 plant sterols, 6.3g carbohydrate, of which 6.3g sugars, 50mg sodium, 140mg calcium

19. Record: 734475, Date: 04 Jul 2007

Milk, White Milk, 1890ml, Shelf stable
Active Lifestyle, Inter-American Products, USA

Description:

Active Lifestyle Milk contains plant sterols, which have been found to help cut the risk of heart disease, and vitamins A and D. According to the company, the product is the first cholesterol-reducing milk to be launched nationally. The product retails in a half gallon pack.

Claims:

Vitamin/Mineral Fortified, Stanols/Sterols

Nutrition Information:

Per serving size 8-fl.-oz. (240ml): energy 90kcal, 0kcal from fat, fat 0g, cholesterol <5mg, sodium 125mg, carbohydrate 13g, fibre 0g, sugars 12g, protein 8g, vitamin A 10%, calcium 30%, vitamin D 25%, vitamin C 4%, iron 0%

20. Record: 678716, Date: 22 Mar 2007

Heart Active Milk, White Milk, 1000ml, Chilled
Pura, National Foods, Australia

Description: New from Pura is Heart Active Milk. It is 99% fat free milk that is said to help lower cholesterol by up to 15%.

Claims: Stanols/Sterols, Low/No/Reduced Fat

Nutrition Information: Per 100g: energy 174kJ/42kcal, 3.3g protein, 1g fat of which 0.5g saturated, >0.1g trans, 0.2g polyunsaturated, 0.2g monounsaturated, 0.32g plant sterols, 4.8g carbohydrate of which 4.8g sugars, 45mg sodium, 123mg calcium

21. Record: 524883, Date: 25 Apr 2006

Cholesterol Reducing Semi-Skimmed Milk Drink, White Milk, 1000ml, Chilled
Tesco, Tesco, UK

Description: Tesco Cholesterol Reducing Semi-Skimmed Milk Drink has been formulated with Reducol Plant Sterol, said to be clinically proven to reduce LDL cholesterol, and is said to be a good source of calcium. This milk is suitable for vegetarians, contains less than 2% fat and retails in a 1L pack. Also available in this range are: Yogurt Drink; and Spread.

Claims: Stanols/Sterols, Vegetarian, Low/No/Reduced Cholesterol, Low/No/Reduced Fat

Nutrition Information: Cholesterol Reducing Semi Skimmed Milk: per 250ml: energy 532kJ/125kcal, protein 7.7g, 13.7g, of which sugars 10.2g, fat 4.5g, of which saturates 3.0g, fibre 0.5g, sodium 0.2g, vitamin B12 1.0µg, calcium 333mg

22. Record: 391044, Date: 18 Aug 2005

Milk, White Milk, 1000ml, Shelf stable
Nestlé Omega Plus, Nestlé, Malaysia

Description:

A fat reduced milk with added plant sterols which are claimed to help lower cholesterol. This product is high in calcium, contains reduced fat and also contains omega 3 and 6. It is halal certified.

Claims:

Halal, Vitamin/Mineral Fortified, Stanols/Sterols, Low/No/Reduced Fat

Nutrition Information:

Per 100ml: energy 196kJ/47kcal, 1.6g fat of which 0.31 monounsaturated, 0.25g polyunsaturated, 0.27g saturated, 0.014g trans fatty acids, 0.21g linoleic acid and 30mg alpha-linolenic acid, 3.1g protein, 5.0g carbohydrate, 180mg calcium, 694IU vitamin A, 24IU vitamin D, 2.7IU vitamin E, 9mg vitamin C, 0.15mg vitamin B2, 49µg folic acid, 0.18µg vitamin B12, 14µg iodine, 160mg sterol

23. Record: 380433, Date: 25 Jul 2005

Milk Powder, White Milk, 1300g, Shelf stable
Nestlé Omega Plus, Nestlé, Malaysia

Description:

Milk powder formulated with ActiCol, with added plant sterols that helps lower cholesterol. The milk powder is claimed to be a breakthrough reduced fat filled milk formulation that has a natural good combination of natural plant sterols and Omega 3 & 6 essential fatty acids. It is claimed that two glasses a day of this milk help reduce cholesterol.

Claims:

Stanols/Sterols, Low/No/Reduced Fat, Functional - Cardiovascular

Nutrition Information:

Per 100g: energy 393kcal/1640, fat 9.4g monounsaturated 2.9g polyunsaturated 2.26, saturated 1.27g, trans fatty acid 0.16g, linoleic acid 343mg, protein 27.0g, carbohydrate 50.0g, moisture 3.5g, sodium 385mg, potassium 1270mg, calcium 1600mg, vitamin A 450µgRE, vitamin D 5.0µg, vitamin E 15 mgTE, vitamin C 75mg, vitamin B1 0.40mg, vitamin B2 1.40mg, niacin 4.8mg, vitamin B6 0.65mg, folic acid 380µg, vitamin B12 2.50µg, iodine 150µg, plant sterol 1.9g

24. Record: 372765, Date: 29 Jun 2005

Milk, White Milk, 1000ml, Chilled
Becel Pro-Activ, Unilever, Denmark

Description:

Maitojuoma is a low cholesterol milk drink with 0.3% fat content. It is packaged in a 1 litre carton.

Claims:

Stanols/Sterols, Low/No/Reduced Cholesterol, Low/No/Reduced Fat

Nutrition Information:

Per 100g: energy 150kJ/35kcal, 3.5g protein, 5g carbohydrates of which 5g sugars, 5g lactose, 0.3g fats of which 0.1g saturates, 0.1g monounsaturates and 0.1g polyunsaturates, 0.3g plant sterols, 0g fibre, 0.1g sodium, 120mg calcium

25. Record: 342140, Date: 22 Feb 2005

Benecol Milk, White Milk, 1000ml, Chilled

Kaiku, Kaiku Corporación, Spain

Description:

Now available in an updated pack with a screw cap is Kaiku Benecol Milk, a skimmed milk with estanol ester which is claimed to reduce cholesterol in just three weeks.

Claims:

Stanols/Sterols, Low/No/Reduced Cholesterol, Low/No/Reduced Fat, Functional - Cardiovascular

Nutrition Information:

Per 100ml: energy 150.9kJ/36.1kcal, 3.20g protein, 4.70g carbohydrates, 0.50g (except stanol) fat, 0.30g stanol*, 120mg (15% rda) calcium (*plant stanols to not contribute to energy value)

26. Record: 307576, Date: 06 Oct 2004

Maitojuoma Milk, White Milk, 1000ml, Chilled

Benecol, Valio, Finland

Description:

An ultra pasteurised milk with added plant stanol and vitamin E. It has a 1.3% fat content.

Claims:

Vitamin/Mineral Fortified, Stanols/Sterols, Low/No/Reduced Fat

Nutrition Information:

Per 100g: energy 180kJ/44kcal, 3.3g protein, 4.8g carbohydrate, 1.3g fat, 120mg calcium, 0.5µg vitamin D

27. Record: 287630, Date: 29 Jul 2004

Pro-Activ Mjölkdryck Milk Drink, White Milk, 1000ml, Chilled

Becel, Unilever, Sweden

Description:

A milk drink with plant sterols that is claimed to lower cholesterol and contains 1.4% fat.

Claims:

Stanols/Sterols, Low/No/Reduced Fat, Functional - Cardiovascular

Nutrition Information:

Per 100g: energy 190kJ/45kcal, 3.4g protein, 5.0g carbohydrate, 1.4g fat of which 0.9g saturates, 0.4g simple saturated, 0.1g poly unsaturated, 0.3g plant sterols, 0.1g sodium, 120mg calcium

28. Record: 287765, Date: 29 Jul 2004

Pro-Activ Semi Skimmed Milk, White Milk, 1000ml, Chilled

Flora, Unilever, Ireland

Description:

Unilever Bestfoods has introduced, under Flora brand, Pro-Activ Semi Skimmed Milk with plant sterols, claims to help maintain a healthy heart and has proven to dramatically lower cholesterol.

Claims:

Stanols/Sterols, Low/No/Reduced Cholesterol, Functional - Cardiovascular

Nutrition Information:

Per 100ml: energy 207kJ/49kcal, 3.6g protein, 4.7g carbohydrate of which 1.8g of sugars, 1.8g fat (excluding sterols) of which 1.1g of saturates, 0.6g monounsaturates, 0.1g polyunsaturates, 0g fibre, 0.06g sodium

29. Record: 274912, Date: 04 Jun 2004

Pro-Activ Milk, White Milk, 1000ml, Chilled
Becel, Unilever, Finland

Description:

A milk drink with plant sterols that is said to help lower cholesterol. This product contains 1.4% fat.

Claims:

Stanols/Sterols, Low/No/Reduced Fat, Functional - Cardiovascular

Nutrition Information:

Per 100ml: energy 190kJ/45kcal, 3.4g protein, 5g carbohydrate of which 5g sugars, of which 5g lactose, 1.4g fat of which 0.9g saturates, 0.4g monounsaturates, 0.1g polyunsaturates, 0.3g plant sterols, 0g fibre, less than 0.1g sodium, 120mg calcium

30. Record: 258761, Date: 04 Mar 2004

Pro-Activ Milk, White Milk, 1000ml, Chilled
Flora, Unilever, UK

Description:

New in the Flora Pro-Activ range is semi-skimmed milk, packaged in a 1 litre carton. The range is said to lower cholesterol, and the milk is priced at £1.19. The company hopes that the new product will be merchandised next to standard milk in the chiller cabinet. Also new under the brand are Pro-Activ yogurts (see relevant category).

Claims:

Stanols/Sterols, Functional - Cardiovascular

Nutrition Information:

Per 100ml: energy 207kJ/49kcal, 3.6g protein, 4.7g carbohydrates of which 4.7g sugars, 1.8g fat of which 1.1g saturates, 0.6g monounsaturates, 0.1g polyunsaturates, 0.06g sodium

31. Record: 163955, Date: 22 Aug 2002

Pro-Activ Milk, White Milk, 0, Chilled
Flora, Unilever, UK

Description:

Unilever is planning to extend its Pro-Activ range of cholesterol lowering products with the introduction of a Milk. Unilever has submitted an application to the UK Foods Standards Agency for its plant sterols to be used in other dairy products.

Claims:

Stanols/Sterols, Functional - Cardiovascular

Nutrition Information:

32. Record: 118661, Date: 23 Oct 2001

Milk, White Milk, 750ml, Chilled
Benecol, Lancashire Dairies, UK

Description:

Lancashire Dairies is under license to make Benecol milk, which contains the patented ingredient plant stanol ester, said to lower cholesterol. The milk has been developed with Benecol brand owner McNeil Consumer Nutritionals. It is packaged in 750ml gable-top cartons, priced at £0.99.

Claims:

Stanols/Sterols, Functional - Cardiovascular

Nutrition Information:

Per 100ml: energy 211kJ/50kcal, 3.4g protein, 4.9g carbohydrates, 1.9g fat, 122mg calcium

33. Record: 82916, Date: 13 Dec 2000

Logicol Milk, White Milk, 0, Chilled
Dairy Farmers, Meadow Lea Foods, Australia

Description:

A pasteurised, homogenised, low fat milk with plant sterols which are said to lower cholesterol absorption. It is packaged in a gable-top carton.

Claims:

Stanols/Sterols, Low/No/Reduced Fat, Functional - Cardiovascular

Nutrition Information:

Per 100ml: energy 224kJ, 4g protein, 6g total carbohydrates of which 6g sugars, 1.4g fat, 0.32g plant sterols, 141mg calcium, 60mg sodium, 183mg potassium

Appendix 4 – UK Milk Sales 2005-2009

FIGURE 24: UK VOLUME RETAIL SALES OF WHITE LIQUID MILK, BY PACKAGING TYPE AND SIZE, 2005-09

	2005 m litres	%	2009 m litres	%
Fresh milk	4,344	90.5	4,554	90.9
<i>of which:</i>				
Glass bottles	523	10.9	306	6.1
Plastic bottles	3,739	77.9	4,153	82.9
<i>of which:</i>				
1 pint (567ml)	202	4.2	240	4.8
2 pints/1.1litres	787	16.4	962	19.2
4 pints/2.2litres	1,882	39.2	1,994	39.8
6 pints/3.3litres	869	18.1	957	19.1
Cartons	82	1.7	95	1.9
<i>of which:</i>				
500ml	24	0.5	30	0.6
750ml	5	0.1	10	0.2
1 litre	53	1.1	55	1.1
UHT	418	8.7	414	8.3
<i>of which:</i>				
0.5 litre	19	0.4	15	0.3
1 litre	326	6.8	321	6.4
6 x 1 litre	72	1.5	80	1.6
 Sterilised	 39	 0.8	 42	 0.8
<i>of which:</i>				
0.5 litre	29	0.6	20	0.4
1 litre	10	0.2	20	0.4
Total	4,800	100	5,010	100

Totals may not equal due to rounding

SOURCE: MINTEL

Milk and Cream, Market Intelligence, May 2010, pp 40-41



Mintel International Group Ltd
18-19 Long Lane
London EC1A 9PL
www.mintel.com
tel: 020 7606 4533
fax: 020 7606 5932
email: info@mintel.com



Australian Government

National Measurement Institute

RE-ISSUED REPORT OF ANALYSIS

Page: 1 of 2

Report No. RN737091

Client	: NATIONAL FOODS LTD 737 BOURKE ST DOCKLANDS VIC 3008	Job No.	: NATI33/090508
		Quote No.	: QT-01453
		Order No.	:
		Date Sampled	: 7-MAY-2009
		Date Received	: 8-MAY-2009
Attention	: Anne Vogelsang	Sampled By	: CLIENT
Project Name	:		
Your Client Services Manager	: Tim Stobaus	Phone	: (03) 9644 4849

Lab Reg No.	Sample Ref	Sample Description
V09/011226	1	05May09 Trial 23:01WP labelled No:1
V09/011227	2	05May09 Trial 23:56WP labelled No:4
V09/011228	3	05May09 Trial 00:55WP labelled No:5
V09/011229	4	Pura heart active 23/05/09

Lab Reg No.		V09/011226	V09/011227	V09/011228	V09/011229	
Sample Reference		1	2	3	4	
	Units					Method
Phytosterols						
Cholesterol	mg/100g	7	7	7	5	VL288
Brassicasterol	mg/100g	< 1.0	< 1.0	< 1.0	< 1.0	VL288
Campesterol	mg/100g	87	91	85	96	VL288
Stigmasterol	mg/100g	56	60	57	65	VL288
beta-Sitosterol	mg/100g	140	150	140	160	VL288
beta-Sitostanol	mg/100g	11	11	12	13	VL288
Total Phytosterol (as above)	mg/100g	330	360	340	370	VL288

V09/011226

Note: The Total Phytosterols (as above) result also includes 32 mg/100g of "other" phytosterols.

V09/011227

Note: The Total Phytosterols (as above) result also includes 38 mg/100g of "other" phytosterols.

V09/011228

Note: The Total Phytosterols (as above) result also includes 35 mg/100g of "other" phytosterols.

V09/011229

Note: The Total Phytosterols (as above) result also includes 31 mg/100g of "other" phytosterols.

Sam Barone, Chemist
Organics - Vic

20-MAY-2009

RE-ISSUED REPORT OF ANALYSIS

Page: 2 of 2
Report No. RN737091

Results relate only to the sample(s) tested.
This Report supersedes reports: *RN736114*
This Report shall not be reproduced except in full.