



AUSTRALIAN
**FOOD &
GROCERY**
COUNCIL

AFGC SUBMISSION

SUBMISSION TO FSANZ –
APPLICATION 1134 INCREASED
CONCENTRATION OF PLANT STEROLS IN

Sustaining Australia

EXECUTIVE SUMMARY

Australian Food and Grocery Council's (AFGC) response to *Application 1134 Increased Concentration of Plant Sterols in Breakfast Cereals*.

Phytosterols and related compounds have an established history of safe use in a wide range of food products in Australia and overseas. The current regulatory permission for their use in breakfast cereals in Australia is too low, not allowing consumers to reach the dietary intakes needed for effective serum LDL – cholesterol lowering solely through breakfast cereal consumption.

FSANZ has made a good case for the benefit to consumers of allowing an effective daily dose of phytosterols in a single serve of breakfast cereal. This argument applies equally well to other food categories restricted in the levels of phytosterol they can contain, and as a result, commercially disadvantaged by A1134 if it is passed. FSANZ should address this inequity by raising a proposal as soon as possible.

FSANZ has completed a risk assessment (Dietary Exposure Assessment and hazard analysis) which comprehensively reaffirms the safety of phytosterols. While endorsing this outcome, the AFGC does not endorse the 'worst case' scenario testing approach used in the analysis. The AFGC counsels FSANZ to adopt a more realistic approach in future, similar risk assessments.

Whilst no substantial risks have been identified by FSANZ associated with raising the permitted levels of phytosterols in breakfast cereals, FSANZ has not referred to the obvious benefits to the community of allowing breakfast cereals on the market with levels of phytosterols, enabling consumers to consume an effective daily dose. The potential reduction of risk of cardiovascular disease to individual consumers and the reduction in cardiovascular disease at the population level has not been used as a justification for extending the regulatory permission. This is an oversight by FSANZ that should be rectified as Application 1134 moves through the regulatory processes.

The AFGC notes that FSANZ has not proposed that the Nutrient Profiling Scoring Criterion (NPSC) be used to disqualify some breakfast cereals from containing phytosterols, a position that the AFGC endorses. The AFGC notes that qualifying criteria of dietary fibre and sugar levels will still apply.

The AFGC supports the suggested amendment to the Food Standards Code as drafted.

RECOMMENDATIONS

The AFGC recommends

- **amendments of the Food Standards Code to extend the permissions for the addition of phytosterols to breakfast cereals as proposed by FSANZ be adopted.**
- **as a matter of urgency that FSANZ develop a proposal for amending the Food Standards Code allowing all current and future food categories permitted as vehicles for phytosterols and related compounds to contain an effective daily dose of up to 2.2g, or equivalent, in a single serving.**
- **FSANZ be more circumspect in future and restrict ‘worst case’ scenario testing for Dietary Exposure Assessment to the plausible but improbable, rather than stretching scenarios to the implausible and impossible.**
- **FSANZ emphasise more strongly the potential public health benefit flowing from extending the regulatory permission for phytosterols in breakfast cereals through amendment of the Food Standards Code.**

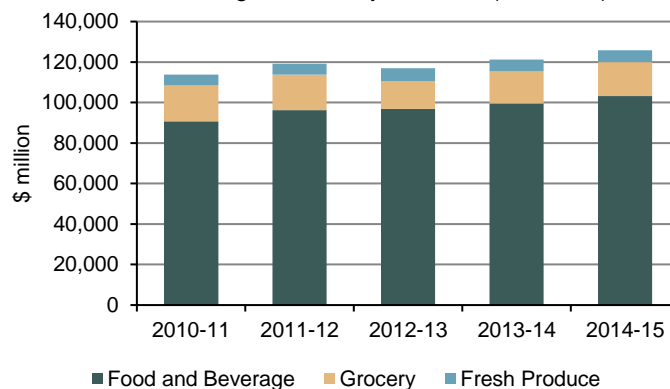
PREFACE

The Australian Food and Grocery Council (AFGC) is the leading national organisation representing Australia's food, drink and grocery manufacturing industry.

The membership of AFGC comprises more than 180 companies, subsidiaries and associates which constitutes in the order of 80 per cent of the gross dollar value of the processed food, beverage and grocery products sectors.

With an annual turnover in the 2014-15 financial year of \$125.9 billion, Australia's food and grocery manufacturing industry makes a substantial contribution to the Australian economy and is vital to the nation's future prosperity.

Figure: Industry Turnover (\$2014-15)



Manufacturing of food, beverages and groceries in the fast moving consumer goods sector is Australia's largest manufacturing industry. Representing 33.3 per cent of total manufacturing turnover, the sector accounts for over one quarter of the total manufacturing industry in Australia.

The diverse and sustainable industry is made up of over 27,745 businesses and accounts for over \$66.6 billion of the nation's international trade in 2015-16. These businesses range from some of the largest globally significant multinational companies to small and medium enterprises. Industry spends \$541.8 million in 2011-12 on research and development.

The food and grocery manufacturing sector employs more than 307,000 Australians, representing about 3 per cent of all employed people in Australia, paying around \$16 billion a year in salaries and wages.

Many food manufacturing plants are located outside the metropolitan regions. The industry makes a large contribution to rural and regional Australia economies, with almost half of the total persons employed being in rural and regional Australia. It is essential for the economic and social development of Australia, and particularly rural and regional Australia, that the magnitude, significance and contribution of this industry is recognised and factored into the Government's economic, industrial and trade policies.

Australians and our political leaders overwhelmingly want a local, value-adding food and grocery manufacturing sector.

INTRODUCTION

The AFGC welcomes this opportunity to respond to Food Standards Australia New Zealand's (FSANZ) Call for Submissions for *Application 1134 Increased Concentration of Plant Sterols in Breakfast Cereals*. In preparing this submission the AFGC has sought the views of its membership. This included major breakfast cereal manufacturers, in addition to some smaller companies, manufacturing breakfast cereal in Australia, as well as the wider AFGC membership. The views of the wider memberships was sought for two major reasons:

- 1) phytosterols, their esters and related stanol compounds are well established, and indeed well accepted, as safe and efficacious serum LDL - cholesterol¹ lowering agents having been introduced into processed foods some 20 years ago, including in Australia. In addition to breakfast cereals there is scope for their addition to many other products thereby extending the opportunity for consumers to access this beneficial functional food component; and
- 2) the recent 'clarification' within food regulatory policy² resulted in applications to amend to the ANZ Food Standards Code (FSC) allowing addition of beneficial food components to foods being subject to greater restrictions. The AFGC views this with some dismay given the outcome of this clarification *may reduce the overall potential public health benefit*³.

There is a long history of safe use of phytosterol-enriched products in Australia and their efficacy in reducing serum LDL-cholesterol when used at appropriate doses is proven. According to the National Heart Foundation (NHF) serum LDL-cholesterol is a leading biomarker risk-factor for Australia's leading preventable cause of premature death – namely cardiovascular disease. Furthermore the NHF recognises the serum LDL-cholesterol lowering properties of phytosterol containing foods⁴.

The AFGC considers it critically important, therefore, that regulatory permissions support the extension of this technology into other food formats and food types, subject to continued safety assessments.

¹ LDL – cholesterol – low-density-lipoprotein cholesterol.

² <http://www.health.gov.au/internet/main/publishing.nsf/Content/foodsecretariat-policy-guidelines#7>

³ Food Standards Australia New Zealand. Assessment against Policy Guideline on Fortification of Food with Vitamins and Minerals (at Review) – *Application A1090 Voluntary Fortification of Vitamin D to Breakfast Cereals. Supporting document 2*. 26 October 2016.

⁴ <https://heartfoundation.org.au/images/uploads/publications/Stanols-QA-General.pdf> Access 10 January 2017.

THE AFGC SUPPORTS A1134

The AFGC strongly supports *Application 1134 Increased Concentration of Plant Sterols in Breakfast Cereals*. The applicants have made a clear case regarding:

- 1) the safety of phytosterols and related compounds at the proposed levels of addition;
- 2) the effectiveness of marketing of phytosterol containing foods which results in the products being consumed almost exclusively by the targeted consumers (men and women seeking to lower their cholesterol levels);
- 3) consumer research indicating the majority of phytosterol food purchasers routinely seek and consume one product only to provide an appropriate dose;
- 4) the efficacy of phytosterols and related compounds in lowering serum LDL-cholesterol levels at the proposed levels of addition into breakfast cereals;
- 5) the current permission within the FSC for phytosterols in breakfast cereals which effectively rules them out from being a practical delivery food for phytosterols; and
- 6) the utility of portion control mechanisms in helping individuals consume precisely the amount of phytosterols required to achieve desired serum LDL-cholesterol lowering effects.

The AFGC notes, however, that *Application 1134* seeks permission to add phytosterols at a higher level in breakfast cereals for products available for sale solely in a portion control format. The AFGC recognises the potential value of portion control formats in assisting consumers to precisely titrate their intake of phytosterols. Notwithstanding this, where phytosterols can be uniformly distributed (and remain distributed without settling) through the bulk of a breakfast cereal product permission should be provided for inclusion of phytosterols at the higher level in formulations.

Recommendation

The AFGC recommends amendments of the Food Standards Code to extend the permissions for the addition of phytosterols to breakfast cereals as proposed by FSANZ be adopted.

IMPLICATIONS FOR OTHER CATEGORIES

The AFGC support for A1134 is based on the evidence that consumers seeking to lower their serum LDL-cholesterol levels would benefit from access to range of products which provide the effective daily dose in a single serve – i.e. 2.2g per serving. This is likely to result in serum LDL-cholesterol level reductions in the order of 9% which is sufficient to reduce heart disease risk significantly (at the population level).

FSANZ has demonstrated that raising the regulatory permissions for phytosterols in breakfast cereals presents no health risk to any population subgroup (even in the worst case scenario).

The argument is strong for extending permission of increased levels of phytosterols in breakfast cereals to levels equivalent to 2.2g / serving to other categories. The AFGC notes, however, that A1134 allows much higher fortification permissions for plant sterols in cereals, compared with milk & yoghurt:

- *Proposed* cereals permission: 0.5-2.2g/serve.
- Milk/ plant sterol permission: 3-4g/L = 0.75-1g/ 250ml serve
- Yoghurt/ plant sterol permission: 0.8 g -1.0 g/package

The rationale for permitting higher levels of phytosterols in breakfast so that an effective daily dose can be consumed in a single serves applies equally well to other food categories. FSANZ should, with urgency, raise a proposal which would allow all current and future food categories permitted as vehicles for phytosterols and related compounds to contain a similar effective daily dose in a single serving. This would:

1. benefit consumers seeking to control their serum LDL – cholesterol levels by providing them with the most convenient options to meet their daily requirements;
2. lead to a greater number of consumers achieving the required phytosterol intake leading to reduced levels of cardiovascular disease at the population level. FSANZ has noted that the current phytosterol intake of consumers is well below the most effective and beneficial daily dose; and
3. remove inequities between food categories. If FSANZ's preferred outcome of A1134 proceeds and the extended permission for phytosterols is provided to breakfast cereals, manufacturers of other products – such as dairy products – will be substantially disadvantaged in the market place.

Recommendation

The AFGC recommends as a matter of urgency that FSANZ develop a proposal for amending the Food Standards Code allowing all current and future food categories permitted as vehicles for phytosterols and related compounds to contain an effective daily dose of up to 2.2g, or equivalent, in a single serving.

COMMENTS ON FSANZ ASSESSMENT

RISK ASSESSMENT

The AFGC has reviewed FSANZ's Risk Assessment (Supporting Document 1) and concurs with its findings. In essence, FSANZ has:

- confirmed once again the substantial body of the evidence supporting the effectiveness of phytosterols in lowering serum LDL levels at the proposed level of inclusion in food breakfast cereal products;
- confirmed once again the safety of phytosterol addition to food products with very limited contraindications being identified by the Dietary Exposure Assessment (DEA) in population sub-groups (e.g. phytosterolaemia, sitosterolaemia).

Notwithstanding this, the AFGC is surprised at the approach taken by the Risk Assessment. FSANZ reported that two scenarios were modelled in the DEA. The first, based on breakfast cereal intake data of population sub-groups as reported in recent National Nutrition Surveys for Australian and New Zealand populations was entirely logical and appropriate. Indeed it confirmed that intakes across all sub-groups would be moderate and well below higher levels which have been demonstrated as being safe.

The AFGC is, however, bemused by the second scenario. The AFGC supports “worst-case” scenario testing, but worst-cases should be plausible, even if highly improbable. The FSANZ scenario which tested phytosterols being added to every breakfast cereal on the market is, frankly, beyond the realms of extreme possibility. This scenario would not happen and the suggestion that it might displays a very poor understanding of the food industry. The exercise simply, but unnecessarily, reaffirmed the very safe nature of phytosterols in foods.

The AFGC does not consider such scenario testing to be warranted. Indeed, the AFGC is concerned that if not challenged, such scenario testing may become routine within FSANZ. At some stage FSANZ will establish a risk associated with an imagined, but highly implausible, worst case scenario. In which case FSANZ will then be in the unviable position of having to explain any action, or indeed inaction, which they subsequently propose.

Risk communication is already challenging enough to lay, or inexperienced, audiences without risk assessment straying into nonsensical scenarios, even when cloaked in apparently learned, technical terminology.

Recommendation

The AFGC recommends FSANZ be more circumspect in future and restrict ‘worst case’ scenario testing for Dietary Exposure Assessment to the plausible but improbable, rather than stretching scenarios to the implausible and impossible.

JUSTIFICATION FOR ADDITION OF PHYTOSTEROLS

One of the fundamental food regulatory principles established for decades in Australia is that nothing should be added to foods unless there is a technical, safety or public health reason for doing so. This is the basis of the FSANZ's approval processes for processing aids, additives, nutritive substances etc. In the FSANZ documentation for Application 1134 it is reported in detail that phytosterols and similar compounds lower serum LDL-cholesterol. This is, of course, a biomarker for cardiovascular disease risk, which FSANZ has failed to directly address in the Risk Assessment report (SD1).

To be clear FSANZ has comprehensively reviewed the scientific body evidence of possible hazards and nutritional consequences of phytosterol ingestion, both acute and chronic. And FSANZ has concluded that the hazards and risks are low for a great majority of the population. FSANZ has also concluded that it is technologically feasible to add phytosterols to breakfast cereals the amounts sought in the Application 1134, with no implication for manufacturing processes.

The primary reason, however, for why phytosterols are added to foods, and primary reason why regulatory approvals are provided is the potential reduction in cardiovascular disease risk for individual consumers, and reduction in the incidence of cardiovascular disease (morbidity and mortality) at the population level.

FSANZ's risk assessment has ignored the potential public health benefit resulting from the addition of phytosterols to breakfast cereals despite the strong association between phytosterol intake, serum LDL – cholesterol levels and cardiovascular disease risk.

Indeed, FSANZ itself has conducted a recent systematic review which confirms the efficacy of phytosterols in reducing serum LDL – cholesterol levels. Within that review FSANZ states⁵

“Reductions in total and low density lipoprotein (LDL) cholesterol are considered to be a beneficial health effect due to elevated levels of these blood lipids being risk factors for coronary heart disease”

The potential public health benefit from adding phytosterols at higher levels in breakfast cereals provides strong justification for extending in the permissions for phytosterols in the FSC.

Recommendation

The AFGC recommends FSANZ emphasise more strongly the potential public health benefit flowing from extending the regulatory permission for phytosterols in breakfast cereals through amendment of the Food Standards Code.

⁵ Systematic Review of the Evidence for a Relationship between Phytosterols and Blood Cholesterol. Food Standards Australia New Zealand. September 2014. www.foodstandards.gov.au

POLICY CLARIFICATION

The AFGC notes the proposed amendment to the FSC continues qualifying criteria (dietary fibre and total sugars) restricting permission for breakfast cereals to contain phytosterols. The AFGC agrees with this approach. The AFGC would strongly oppose the Nutrient Profiling Scoring Criterion be used to disqualify breakfast cereals from phytosterol inclusion. FSANZ points out that the NPSC applies only to *Standards 1.2.7 Nutrition, Health and Related Claims* and is not designed to restrict the composition of food products in any way. The recent use of the NPSC restricting addition of Vitamin D to breakfast cereal as a result of the ‘policy clarification’ by the Forum on Food Regulation and use of the NPSC was assessed by FSANZ as leading to a possible reduction in public health benefit. Application of the NPSC restricting phytosterol use would risk similar reductions in public health benefit.

CONCLUSIONS

The AFGC continues to support innovation in the food industry leading to new food products which assist consumers construct health diets and meet their individual nutrition and health needs. Phytosterols are demonstrably safe and effective in reducing biomarkers for disease risk. As such they represent an almost perfect functional ingredient suitable for addition to a wide range of food products. The challenge for FSANZ and the regulatory system is to ensure regulations facilitate their responsible use by the food industry so maximum benefit can accrued to the community. In doing so FSANZ should also be wary of distorting the market by relaxing or restricting the permissions for phytosterols or other functional ingredients without a clear public health and safety reason. If there is a risk of market distortion FSANZ should act to address it also ensuring consumers have ready, convenient access to food products and the benefits they can provide. The AFGC stands ready to provide further input to help Application 1134 secure an appropriate amendment to the Food Standards Code.