



AUSTRALIAN
**FOOD &
GROCERY**
COUNCIL

AFGC SUBMISSION

RESPONSE TO FSANZ CONSULTATION
PAPER – W1109 – CONSULTATION ABOUT
BETA-GLUCAN AND BLOOD
CHOLESTEROL HEALTH CLAIMS.

Sustaining Australia

SUMMARY

The Australian Food and Grocery Council (AFGC) welcomes the opportunity to make this submission in response to *Consultation Paper – W1109 Consultation about beta-glucan and blood cholesterol health claims*.

The AFGC considers that in conducting the systematic review and developing the consultation paper Food Standards Australia New Zealand (FSANZ) has made some fundamental errors which have resulted in the flawed conclusion that amendments to the Food Standards Code are required.

In brief, FSANZ has decided to:

- 1) ignore the intent of *Standard 1.2.7 Nutrition Health and Related Claims* which is to set a framework of companies' innovation leading to better products with appropriate claims, able to protect and promote better health outcomes for Australians,
- 2) set unrealistic and ill-informed requirements for demonstrating the biological activity of a naturally occurring food component in random controlled trials,
- 3) settled on a determination which conflicts with previous FSANZ findings, and runs contrary to the scientific opinion of other competent authorities when current Australian Government policy is to recognise regulatory approvals made by competent authorities such as the European Food Safety Authority, Health Canada and the Food and Drug Administration with a view to alignment,
- 4) ignores its own *Nutrient Profiling Scoring Criterion* as a risk management tool designed to provide a mechanism which allows health claims with lower evidence grades on food products which by virtue of their nutrient profile are aligned with the Australian Dietary Guidelines, and
- 5) adopt a path, which if taken to its logical conclusion, will substantially disrupt the marketing of products threatening not only current and future business planning, but also consumer understanding of the nutritional value of a range of products on the market.

If this consultation (W1109) results in an amendment to the Food Standards Code which FSANZ indicates may be an outcome it will:

- be on the basis of an out of date systematic review which reveals shortfalls in FSANZ's understanding of fundamental statistical principles (probability, confidence intervals and certainty) and a poor knowledge of the properties of non-starch polysaccharides from plant cell walls, and their physiological activities;
- set an impractical hurdle for demonstrating physiological or nutritional activity of food components – namely requiring 100% purity which is technical impossible to achieve or demonstrate; and
- most probably be done in the complete absence of any demonstrable consumer harm arising from the current use of health claims.

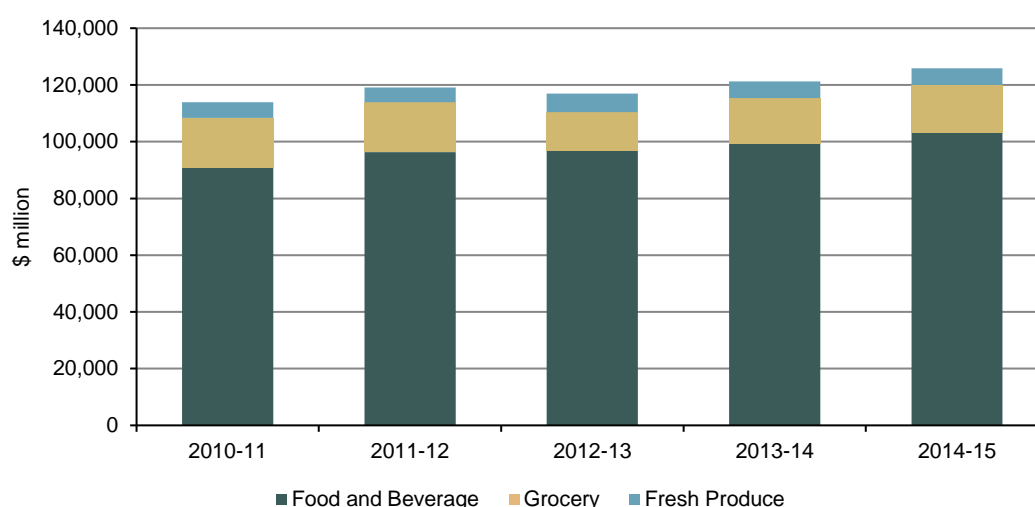
The AFGC recommends that FSANZ abandon W1109 and devote more time to aligning *Standard 1.2.7 Nutrition, Health and Related Claims* with international approvals to encourage the development and promotion of new products as was anticipated.

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.

Composition of the industry's turnover (\$2014-15)



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.

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 Australian Food and Grocery Council (AFGC) welcomes this opportunity to respond to the Food Standards Australia New Zealand (FSANZ) *Consultation Paper – W1109 – Consultation about beta-glucan and blood cholesterol health claims*.

The submission is in two parts:

- **General comments** in which the AFGC makes a number of observations and comments regarding the beta-glucan and cholesterol-lowering health claim and FSANZ's assessment of it; and
- **Specific comments** in response to the questions raised in the consultation paper.

The submission was prepared following consultation and feedback from a number of AFGC member companies.

GENERAL COMMENTS

The AFGC does not support the position FSANZ has taken in the Discussion Paper. The AFGC is highly critical of the rationale behind the positions FSANZ has taken. FSANZ shows a rigidity of approach which is not technically or scientifically sound, and inappropriate when applied to health claims on food products. The approach seems to be designed to make the use of nutrition, health and related claims by food companies as difficult as possible. The AFGC has voiced concerns in the recent past regarding FSANZ's management of health claims, and this latest effort by FSANZ adds to those concerns.

1. FSANZ is failing to reflect the intent of Standard 1.2.7

The AFGC reminds FSANZ that when *Standard 1.2.7 Nutrition, Health and Related Claims* was gazetted in 2013 it was announced by FSANZ with considerable fanfare. The standard, FSANZ stated, heralded a new era of opportunity for the Australian and New Zealand food manufacturers encouraging innovation leading to products better able to protect and promote better health outcomes for Australians and New Zealanders. FSANZ's conclusions in *W1109* are in direct conflict with the original intent of Std.1.2.7. which was to allow substantiated health claims. It was not envisaged, and certainly not intended, that level of substantiation required by FSANZ would be somewhat arbitrary and subject to FSANZ-specific hurdles not applied by other competent authorities regulating health claims overseas. FSANZ's approach sends the wrong signal to industry that innovation is not only discouraged, but that FSANZ is prepared to reverse previous assessments which ultimately will impose greater regulatory restrictions on industry.

2. FSANZ is failing to set sensible substantiation requirements

The AFGC rejects the two FSANZ assertions which form the basis for their rejection of, and potential removal of approvals for, cholesterol-lowering claims related to barley and to beta-glucan.

Barley cholesterol lowering effects

FSANZ asserts that a simple subject count in random controlled trials (RCTs) is enough to discount the finding of a treatment effect downgrading the "strength of evidence" to "moderate". This ignores the statistical concepts of 'significance' and 'power' within an individual RCT and when considering systematic reviews. The AFGC notes that FSANZ decided that despite the magnitude of the cholesterol lowering effects being greater in the combined barley RCTs, FSANZ determined the evidence for the effect was weaker than for the combined oat trials, on the basis their fewer subject numbers.

The AFGC understands that whilst greater numbers of subjects provides more power to experiments (i.e. more sensitivity to detect real effects, at high levels of confidence), statistical analysis resulting in '*p values*' provides a means of assessing the probability of an effect being real, irrespective of the number of subjects in the trial. This is therefore a measure of certainty. The systematic reviews (SR) conducted by FSANZ

suggests with the same level of certainty that the both oats and barley do lower LDL-cholesterol and total cholesterol with barley having a greater effect – and both have substantial effects (see Table).

Material	LDL – Cholesterol			Total Cholesterol		
	mmol/L	p value <	95%CI	mmol/L	p value	95%CI
Oats	-0.21	0.00001	-0.24 -0.17	-0.22	0.00001	-0.27 -0.17
Barley	-0.25	0.00001	-0.32 -0.18	-0.32	0.00001	-0.42 -0.21

Furthermore, the AFGC notes that the lower limit of the 95% confidence interval for LDL – cholesterol lowering and total cholesterol lowering for barley is very similar to the mean cholesterol lowering values (-0.21mmol/L and -0.22mmol/L respectively) of oats. If the magnitude of cholesterol lowering recorded for oats is of substantiated public health significance (as concluded by FSANZ), then based on the advice of the Cochrane organisation¹ with respect to levels of evidence in measuring treatment effects; vis:

***Level I.** For a randomised controlled trial, the lower limit of the confidence interval (expressed as a range) for a measure of effect is still above a meaningful benefit in healthcare terms*

***Level II.** For a randomised controlled trial, the lower limit of the confidence interval (expressed as a range) for a measure of effect is less than a meaningful beneficial effect in healthcare terms; but the point estimate of effect still shows effectiveness of the intervention*

the magnitude and confidence intervals recorded for barley indicated it would not be unreasonable to assume that the barley cholesterol-lowering effects are real, at least as great as oats, and therefore substantiated. This does not support FSANZ's conclusions that supporting evidence for the barley cholesterol lowering claim is only moderate.

The AFGC understands that when conducting systematic reviews and meta-analyses best practice requires the identification of an appropriate 'standard of proof' value prior to work being undertaken. This is a precaution against researcher bias. For example a value of 0.01 (relatively conservative) might be set for *p* which means that there is 1 chance in 100 of accepting a treatment effect when the result was due to chance (i.e. Type II error). FSANZ is concerned that there were relatively low subjects numbers (~200) in the studies included in the barley meta-analysis. Nevertheless the data (reproduced in the table above) shows that a *p*<0.00001 for both the total cholesterol and LDL-cholesterol figures. This means that there is 1 chance in 100,000 that the cholesterol lowering values for barley occurred by chance. Additional subject numbers would only serve to reduce (or tighten) the confidence intervals or increase the significance of data that were already found to be statistically highly significant. Additional subjects would not reverse the association between barley and blood cholesterol.

FSANZ appears to have relied on Cochrane GRADE methodology in downgrading the evidence the barley cholesterol-lowering claim using the GRADE methodology from the Cochrane Collaboration. The Application Handbook, however, does not insist on the use of GRADE, but rather requires a "high degree of certainty" in the relationship. Indeed, the "litmus test" of this relationship is whether a single high-quality study could overturn the relationship. In the case of barley, although only seven studies were included, every study demonstrated a reduction in blood cholesterol. The resulting *p* value was < 0.00001. An analysis of the data show that using the average standard error of 0.13, a study which might challenge the veracity of the barley cholesterol lowering claim would have to show an *increase in cholesterol* of 0.6 mmol/L in order to bring the *p* value to 0.05 (Figure). This value is three times the average change in cholesterol, in the opposite direction. The chance of this occurring is very small, again confirming that there is a very high likelihood that the claim is in fact correct.

¹ <http://consumers.cochrane.org/cochrane-and-systematic-reviews>

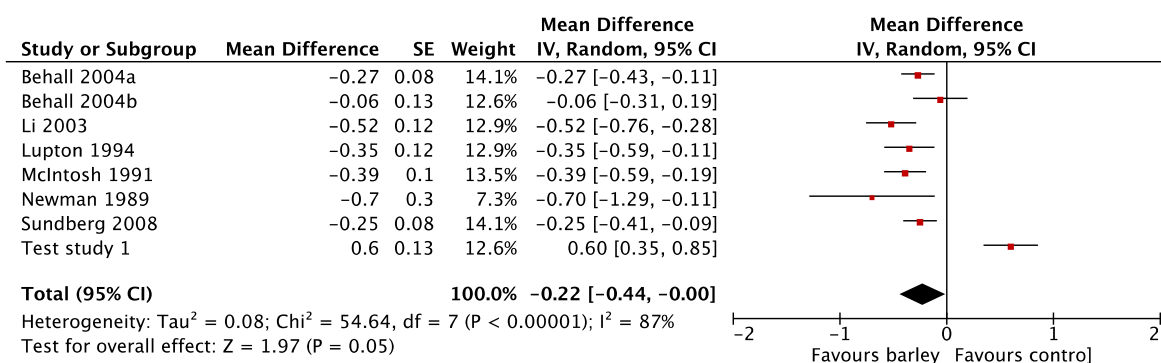


Figure: Theoretical analysis of the effect size required to overturn the FSANZ assessment

Given this, The AFGC calls into question the use of an extremely high bar (GRADE) for what is only a label on food. The GRADE methodology was designed to assess the weight of evidence for medical interventions (such as pharmaceutical drugs), which are not only a high burden to the taxpayer if ineffective, but are also potentially harmful (in terms of adverse events). Neither of these is the case for food.

Overall, the AFGC considers there is no firm justification for downgrading the evidence assessment to 'moderate'.

FSANZ should clearly indicate whether before conducting the systematic review they determined standards of proof, and their rationale for doing so, particularly focusing on why they are imposing levels of evidence (i.e. burdens of proof) designed for medical interventions on relatively benign food health claims. Otherwise, the AFGC can only assume the decision to downgrade the level of evidence for the barley claims was at best arbitrary, and at worst a deliberate attempt to restrict the use of health claims by industry.

Recommendation

The AFGC recommends that FSANZ re-assesses the cholesterol-lowering effects of barley and be guided by accepted statistical methodology and approaches to assessing strength of evidence, rather than simply downgrading the evidence based on number of subjects alone.

Beta-glucan cholesterol lowering effects

FSANZ states that as there are no studies utilising 100% pure beta-glucan no assessment can be made to substantiate the beta-glucan cholesterol lowering claim. The AFGC is astounded that FSANZ has made this statement. The corollary is that virtually no substances derived from biological materials or produced on an industrial scale can be assessed for physiological effects. Taking the FSANZ assertion to its logical conclusion means that much of the evidence of modern nutritional science now has to be questioned. Classic nutrition experiments which identified the activities of micronutrients now have to be discarded, as none of them would have been isolated in 100% pure form.

The AFGC agrees with FSANZ that beta-glucan, in common with other plant non-starch polysaccharides, is difficult to extract and isolate to high levels of purity, particularly in the quantities required for feeding experiments. Moreover, extraction procedures themselves can result in fractionation of the polysaccharides and some alteration of the physico-chemical properties. Nevertheless, there is good information from animal studies and in-vitro experimentation that many of main properties of non-starch polysaccharides attributed to their polymeric nature (viscosity, gel forming, chelation) are retained at least to some degree. When ingested, they mimic the physiological effects associated with whole grains consumption.

FSANZ acknowledges that beta-glucan is the likely cholesterol lowering component in both oats barley through reference to there being a plausible mechanism. FSANZ has noted that other soluble fibres (such as arabinoxylans) may contribute to the cholesterol lowering activities. The AFGC agrees with this statement but points out that the levels of both classes of polysaccharides can change quite significantly in terms of their levels and physical properties even within individual cereal types. In general, however, cereals such as wheat and rye tend to have relatively high levels of arabinoxylans, and lower levels of beta-glucan, whilst for oats and barley the opposite is the case – beta-glucans tend to dominate.

The reality is that there is a substantial body of evidence which demonstrates that beta-glucan enriched cereal fractions have cholesterol lowering activity. This body of evidence should be assessed by FSANZ comprehensively, rather than dismissed out of hand, simply because of the artificial, and quite frankly nonsensical 100% purity requirement. At best this reveals a formulaic, rather than expert, approach by FSANZ to the substantiation of food/health relationships, or at worst is another example of FSANZ attempting to restrict the use of health claims by industry.

Recommendation

The AFGC recommends that FSANZ conduct a formal assessment of the cholesterol lowering claims related to beta-glucan discarding the unrealistic 100% beta-glucan purity requirements of experimental cereal fractions.

3. FSANZ is failing to note findings of other competent authorities

The AFGC is surprised that FSANZ is effectively overturning the advice of other competent authorities which include the European Food Safety Authority, the US Food and Drug Administration, Health Canada and FSANZ in 2006. Taken in their entirety the health claims allowed in overseas jurisdictions leave little doubt that these competent authorities consider the evidence of oats and barley having cholesterol lowering effects is strong, and that the active component is beta-glucan. FSANZ may choose to split hairs by pointing out that differences in terminology but when it comes to the terms 'dietary fibre', 'soluble fibre' or 'beta-glucan' but they are all essentially synonymous when considering oats and barley, and their cholesterol lowering effects.

FSANZ reviewed the evidence of supporting beta-glucan claims and cholesterol lowering in 2006 and consequently allowed the approved associated claims in schedules to Std. 1.2.7. The current systematic review which FSANZ has now completed appears to include a good portion of earlier studies (i.e. pre 2006)² as well as more recent studies. With regard to the studies relevant to barley, only one paper from seven appears to be more recent than 2006 suggesting the other six contributed to FSANZ's earlier conclusions which led to their support of the barley/cholesterol lowering relationship. As the additional study supported relationship, the AFGC does not agree that FSANZ now has sufficient grounds for disallowing the barley/cholesterol lowering claim. FSANZ claims the latest systematic review suggests changes need to be made to the allowed claims to maintain the currency of the Food Standards Code. This is not the case. The additional study in review confirms the findings of previous studies and therefore supports the previous assessments.

Recommendation

The AFGC recommends FSANZ maintain the current permissions for health claims for oats, barley and their beta-glucans in line with claims allowed overseas, and in the absence of convincing evidence that these claims are false.

The AFGC also notes that current Australian government policy is to recognise the regulatory approvals of overseas competent authorities. The AFGC is aware FSANZ is bound to *consider* the findings of other competent authorities, but is not bound to accept them. The AFGC is also aware that FSANZ considers some overseas jurisdictions, and in particular, the EU, do not put sufficient rigour in their assessment of health

² The AFGC has not laboriously gone through reference lists from the earlier reviews.

claims. The AFGC fully supports rigour in scientific assessments, but ultimately that rigour needs to be tempered by the concepts of proportionate response, and the risk of harm being balanced against the overall benefit.

The AFGC would be gravely concerned if the FSANZ decided to move away from the current alignment regarding oats, barley and beta-glucan cholesterol lowering claims on the basis the ill-founded premises within the systematic review.

4. FSANZ is failing to allow the NPSC to fulfil its function

When Std. 1.2.7 was introduced the Nutrient Profiling Scoring Criterion (NPSC) requirements were included as a risk management tool. FSANZ argued that health claims should only be allowed on foods which met specific nutrient profiles – essentially lower levels of risk associated nutrients and high levels for positive nutrients. The NPSC prevents health claims being carried on products high in energy, saturated fat, sugars, and sodium (no matter how strong the evidence might be demonstrating risk-reduction effects).

In practice, however, FSANZ is not allowing the NPSC for fulfil its function to the extent that it might to encourage healthy diet construction. FSANZ maintains that it is necessary to have high levels of evidence to support all health claims. Claims supported by moderate levels of evidence appearing on foods which pass the NPSC are still be likely to be better dietary choices than foods which are not making any claims – simply by virtue of their nutrient profile. Moderate levels of evidence still suggest consumers will receive a benefit and coupled with the NPSC restrictions the risks of negative outcomes for consumers would be low.

Recommendation

The AFGC recommends that FSANZ allows the risk management function of the Nutrient Profiling Scoring Criterion to provide the consumer protection for which it was designed, and recognise the overall value of a continuing to support a cholesterol reduction claim for barley and beta-glucan.

5. FSANZ is failing to acknowledge current commercial realities.

FSANZ's systematic review and consultation document foreshadow amendments to the FSC which would effectively remove regulatory permission for health claims which:

- had previous been substantiated and approved in Australia and jurisdictions overseas based on formal assessment of supporting evidence;
- are now well established in the market place supporting products and brands which are well accepted by consumers, and
- threatens substantial costs on companies currently using the claims due to new label development and printing, new product development (possible change in ingredients) and development of new points of differentiation and marketing of products.

6. FSANZ has failed to present its analysis in a reasonable timeframe

The AFGC notes that the systematic review includes literature up until December 2014. Taking almost three years to conduct a systematic review and release a consultation paper has two consequences:

- a) it signals that FSANZ considers there is a little or no risk of substantial harm to consumers if the claims currently in the market place regarding barley and beta-glucan cholesterol lowering are false;
- b) the usefulness of the systematic review and its authority to guide regulatory decisions are devalued as more studies are published, and indeed this has happened and they support the fundamental contention that wholegrain oats and barley when included in the diet do have cholesterol lowering effects, most likely due to the beta-glucan content..

SPECIFIC COMMENTS - RESPONSES TO FSANZ QUESTIONS

1. **What do you consider to be the best approach for managing this food-health relationship in the Code, given the outcomes of the systematic review for the food-health relationship for a HLHC about beta-glucan? (see Section 7.1) Please give reasons for your response.**

The AFGC is not convinced the FSANZ Systematic Review provides enough evidence to support any amendment of the Food Standards Code. The AFGC has made its views clear on the shortcomings of the Systematic Review and conclusions drawn from it. FSANZ has clarified that human clinical research with *purified* beta-glucan has not and is unlikely to be conducted in the future for practical or feasibility reasons. However, the results of the systematic review confirm the strong effect of both oats and barley as sources of beta-glucan to reduce blood cholesterol concentrations.

2. **What do you consider to be the impacts of amending the Code for consumer understanding about beta-glucan, oats and barley and blood cholesterol?**

The AFGC is concerned that consumers will generally react unfavourably to any changes in food labelling which suggests that previous labels carried false claims. This has the potential to reflect negatively on products and brands and on brand owning companies. Furthermore it will undermine consumer confidence in the food industry more broadly and it will bring into disrepute Australia's food regulatory system. There is already concerns among consumers regarding shifts in nutritional science which seem to reverse or overturn previous dietary advice. The reality is, however, that basic dietary advice has not really change, except for a few cases. The removal of approval for the beta-glucan health claim risks being portrayed as nutritionist getting it wrong again which is not good for consumers, for regulators or industry.

3. **Do you consider that such amendments to the Code would be consistent with dietary guidelines and other relevant public health messages? Why/why not?**

The amendments to the FSC would be inconsistent with the general advice in the Australian Dietary Guidelines (ADG) which recommend the consumption of whole grains, including barley. The amendments effectively erode the nutritional value of barley compared to oats. This is not reflected in the ADG.

In the longer term a rift will develop between the FSC and the ADG and other dietary guidelines. This will be a direct consequence of the precedent for substantiation of health claims regarding the efficacy of nutritive substances to be based on evidence from RCT utilising 100% pure preparations. The net result will be a chilling effect on product innovation and claims on products as food industry will be hindered in developing products which are aligned to the dietary guidelines.

4. **What do you consider to be the impacts on the food industry of such an amendment?**

The AFGC is aware that food manufacturers are already finding it difficult to work within the current requirements of Std. 1.2.7. The raising of the bar for substantiation of claims by FSANZ, the risk of reversal of regulatory approval and lack of for application of the concept of proportionate risk will discourage companies from seeking to develop products making health claims. Industry will be discouraged to seek market differentiation based on a health platform which in the longer term may hobble their competitiveness in global markets.

Failure by FSANZ to be more specific about standards of proof, which has been highlighted as a major shortcoming in FSANZ's systematic review, as described above. FSANZ should be more transparent and technically rigorous in setting standards of proof for substantiation of health claims. Food industry is reticent to invest in innovation as it is unclear what is required for a health claim to be approved.

5. **What foods do you sell that currently carry health claims (GLHC or HLHC) about beta-glucan? Please provide the following information for these foods:**

This question is not applicable to the AFGC.

CONCLUSIONS

The AFGC retains grave concerns regarding the systematic review FSANZ has conducted, and the conclusions they have drawn from it. The consultation paper perpetuates the fears that the AFGC has that under the current policies of FSANZ the intent is to use Standard 1.2.7 Nutrition, Health and Related Claims to hinder industry and its development of new products aimed at improving the health of consumers. Rather than providing facilitating regulatory guidance FSANZ seeks to hinder industry to the extent that it is prepared to put its own reputation for scientific expertise at risk.

FSANZ would do well to simply abandon W1109 – the claims for oats, barley, and beta-glucan are valid, they appear on core food products which meet the NPSC requirements. There is no justification for changing the current arrangements, and none is likely to come forward.