FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

26 October 2016
[26–16]

Supporting document 3

Summary of review submissions – Application A1090

Voluntary Addition of Vitamin D to Breakfast Cereal

The following is a summary of issues raised by submitters and, where appropriate, FSANZ's response to the issue. Some submitters provided fall-back positions if their preferred position was not reflected in the approved draft variation following the review.

Applying the NPSC to breakfast cereal fortification with vitamin D	Submitter	FSANZ response
Supports proposed option to limit vitamin D fortification permissions to only breakfast cereal that meets the NPSC.	Some jurisdictions (NSW, Victoria, Tasmania, WA)	Noted. See Review Report, particularly section 8.
Supports the fortification of breakfast cereal with vitamin D – either restricted to cereals that meet the NPSC or all cereals	MPI	Noted.
Supports/ prefers the voluntary addition of vitamin D to all breakfast cereal	Industry and one jurisdiction (Nestlé, AFGC, Sanitarium, GLNC, Kellogg, MPI)	Noted.
Recommend the Application not be approved	Public health organisations (Deakin University, PHAA, CCA)	Noted. However, FSANZ does not agree. FSANZ has assessed the voluntary fortification according to the FSANZ Act, and considers that it is safe and provides additional choice to consumers who may wish to increase their dietary vitamin D intake.
If the voluntary addition of vitamin D to breakfast cereal were permitted, it should be permitted only for those cereals that meet the NPSC.	Public Health Organisations (PHAA, CCA, OPC)	Noted. See Review Report, particularly section 8.
Applying the NPSC to voluntary fortification of breakfast cereal with vitamin D is consistent with the specific policy principles in the Ministerial Policy Guideline.	Jurisdictions) (NSW, Vic, Tasmania, WA, Qld, MPI)	Noted. See SD2.

Breakfast cereals and Dietary Guidelines	Submitter	FSANZ response
Breakfast cereals are considered a core food.	MPI	Noted. See Review Report, particularly section 4.
Only those breakfast cereals that are not high in added salt, sugar and fat are included as a core food in the Dietary Guidelines.	Qld, NSW	Noted. See response above.
As core grain foods, the consumption of RTE breakfast cereal is consistent with both countries' Dietary Guidelines and does not contribute significantly to added sugar, salt or sat fat intakes regardless of whether the breakfast cereal meets the NPSC.	GLNC, NZFGC, Kellogg	Noted. See response above.
Using nutrient profiling to discriminate between breakfast cereals does not align with the Dietary Guidelines.	Kellogg, GLNC	Noted.
Breakfast cereals classified as discretionary are higher in sugar. However, they contribute minimally to the average Australian diet making the restriction of vitamin D fortification in these cereals largely unnecessary.	GLNC	Noted. See Review Report, particularly section 4.

Public health and safety	Submitter	FSANZ response
Public health and safety is protected regardless of whether the NPSC is applied to the permission to fortify breakfast cereals with vitamin D.	GLNC	Noted.
Public health is better served by permitting the addition of vitamin D to all breakfast cereal without any overlying NPSC like qualification filter.	AFGC	Noted.
Restricting fortification may increase the cost of these 'healthier' cereals which could impact those in low socioeconomic groups who cannot afford to purchase higher priced cereals. This could increase the health gap further for low income groups.	DAA	Noted. See Review Report particularly section 9.
It is not in public health interest to introduce a regulation that will potentially increase the cost of core grain foods.	GLNC	Noted.
Not all breakfast cereals that fail the NPSC are high in sugar or targeted to children. For example corn flakes and puffed rice do not meet the NPSC yet are affordable, low cost family cereals that would be prohibited from adding vitamin D if the NPSC is applied.	Sanitarium	Noted. The NPSC takes sodium and saturated fat in addition to sugar and energy content into account and contains offsets to allow for sugar contained in fruit, protein and fibre content.
Applying the NPSC protects public health and safety because it provides consumers the option to choose a vitamin D fortified cereal, but ensures the vitamin D fortified cereal is not high in salt, sugar or fat.	Victoria	Noted.

Public health and safety	Submitter	FSANZ response
Restricting fortification will not achieve measurable obesity reduction, but suggests such a restriction is suitable to provide a reformulation incentive.	NSW	Noted. As explained in section 6 Review Report, the effect of the NPSC requirement itself for driving industry to reformulate their product ranges is unknown.
Fortification of less healthy cereals may increase consumption of these cereals and may have an adverse effect on public health and lead to obesity and associated chronic disease.	OPC	Noted.
No evidence presented to prove that vitamin and mineral fortification leads to the promotion of foods high in sugar, salt and saturated fat which then results in non-compliance with the policy guideline	Kellogg	Noted.

Health Benefit vitamin D fortification	Submitter	FSANZ response
Acknowledge there are potential health benefits of receiving adequate levels of dietary vitamin D through fortification of breakfast cereals with vitamin D.	MPI, GLNC	Noted.
There is limited evidence demonstrating that vitamin D fortification delivers health benefits.	CCA, OPC	Noted. FSANZ is satisfied that the evidence indicates a potential health benefit. See Technological and Nutrition Risk Assessment at Approval, and SD2 of the Review Report. Because voluntary fortification depends on both industry adding it and consumer consuming the product, FSANZ can demonstrate a potential benefit only.
Excluding 15% of the breakfast cereal market will have minimal impact on health benefit.	NSW, Tasmania, MPI	Noted. See Review Report, particularly section 6.
Specific subgroups of the population are likely to benefit more from vitamin D fortification by removing the nutrient profiling restriction to fortification. • 20% of Australians over 75 were vitamin D deficient, • Limited data on prevalence of vitamin D deficiency in children. These may be an at risk group. • Breakfast cereal consumption is highest in these age groups. • More high sugar breakfast cereals are consumed by children.	Kellogg	Noted.
The less nutrient dense cereals tend to be consumed by children aged 2–8 years. This age group may benefit from vitamin D fortification more than older children or young adults.	MPI	Noted.
The modelling of vitamin D fortification on	Kellogg	Noted. See response above.

Health Benefit vitamin D fortification	Submitter	FSANZ response
serum levels presented underestimates the potential benefit of vitamin D fortification of breakfast cereals. (It excludes NZ population who are at higher risk of vitamin D deficiency, and children under 12 who are highest consumers of breakfast cereal)		Biomedical data were not available for these population groups. FSANZ based its assessment on the best available scientific evidence.
Public health and safety is not protected by applying the NPSC to permission to fortify breakfast cereal with vitamin D. This is because any decrease in supplementation through breakfast cereal must have a negative impact on the range of musculoskeletal disease that would outstrip unknown, prospective but potentially nil benefits of limiting the fortification of breakfast cereals with vitamin D.	NZFGC	Noted. However, Vitamin D fortification is not currently permitted, so a permission to add to any food could only have a neutral or positive effect on musculoskeletal disease.

Health Benefits of breakfast cereal – nutrient intakes, weight, milk intake	Submitter	FSANZ response
The proposal does not account for the significant positive contribution breakfast cereals make to daily nutrient intakes, regardless of their nutrition profile, and without contributing excess amounts of sugar, salt and fat.	Kellogg, AFGC, Sanitarium, NZFGC,	Noted. However, the scope of this Review was to assess the addition of vitamin D to breakfast cereals. Assessing the benefits of breakfast cereal *per se* in the diet was beyond the scope of this Review report. See also section 4 of the Review Report.
The benefits of all breakfast cereal remain as they are all nutrient dense and provide key nutrients to the diet.	Nestlé, Kellogg	Noted. However, the Review focused on the addition of vitamin D to breakfast cereal, rather than the benefits of breakfast cereal *per se*. See also section 4 of the Review Report.
Breakfast cereal consumers have better micronutrient intakes than non-consumers irrespective of the total sugars content of the breakfast cereal. Also, cereal consumers have healthier body weights than consumers of other breakfasts.	Kellogg, Nestlé, GLNC, NZFGC	See section 4 of the Review Report.
All breakfast cereal, irrespective of their nutrient profile play an important role in facilitating milk consumption and increasing calcium intakes among children and adolescents.	Kellogg, NZFGC	See section 4 of the Review Report.

Vitamin D2	Submitter	FSANZ response
Restrict fortification of breakfast cereals to D3 only, because vitamin D2 is not safe	CCA, OPC	FSANZ does not agree. FSANZ assessed the safety of vitamin D2 and D3 in the Technological and Nutrition Risk Assessment at Approval. The new evidence presented in this submission did not change the conclusions of that review

Salience of vitamin D	Submitter	FSANZ response
It is likely vitamin D will have a heightened effect on consumer behaviour than other vitamins or minerals.	OPC	Noted. See Review Report, particularly section 5.1.
Doubt as to whether vitamin D enjoys any special status in driving choice amongst breakfast cereal consumers than any other vitamin or mineral.	AFGC	Noted. See Review Report, particularly section 5.1.
Without consumer education the difference between consumers' response to the presence or absence of vitamin D in food would be very low compared to presence or absence of other vitamins.	GLNC	Noted. See response above.
Consumers may be more likely to be influenced by a claim about vitamin D on a breakfast cereal product than they would be about other vitamins and minerals, including those already permitted.	OPC	Noted. See response above.

Claims, health halo and misleading	Submitter	FSANZ response
A vitamin by its presence in a food (and its associated nutrition content claim) has an implied health effect.	NSW, Victoria, OPC	Noted. All food, including breakfast cereal, is able to carry nutrition content claims for all other added vitamin and minerals providing certain requirements are met in accordance with Standard 1.2.7. See Review Report, particularly section 5 and SD4, which reviewed the literature relating to consumer response to nutrition content claims.
Fortifying cereal with vitamin D without meeting the NPSC permits foods higher in saturated fat, sugar and salt to make nutrient content claims and therefore encourage consumption of these cereals.	Victoria, CCA, OPC	Noted. All food, including breakfast cereal, is able to carry nutrition content claims for all other added vitamin and minerals providing certain requirements are met in accordance with Standard 1.2.7. See Review Report, particularly section 5 and SD4, which reviewed the literature relating to consumer response to nutrition content claims.

Claims, health halo and misleading	Submitter	FSANZ response
Restricting permission to add vitamin D will assist in minimising the health halo effect that could have otherwise been attributable to energy dense, nutrient-poor discretionary cereals.	NSW	Noted.
Applying the NPSC ensures that a content claim about vitamin D does not provide a misleading impression of the overall nutritional quality of cereals.	Victoria	Noted.
Even if fortification of all breakfast cereal were to result in vitamin D nutrient content claims on less healthy breakfast cereals, FSANZ indicates that consumer research shows that the presence of a claim does not alter consumers perceptions of the nutritional value or healthiness of a product when they have access to standard on –pack nutritional information such as the statement of ingredients and the NIP.	MPI	Noted. See Review Report, particularly section 5.
Voluntary fortification is used by manufacturers to support marketing activities.	Deakin University, CCA, OPC	Noted. Food and other laws in Australia and New Zealand have general provisions to ensure that marketing of food products is not misleading or deceptive.
Concern that vitamin D fortification in all breakfast cereals could inadvertently provide a new marketing opportunity for discretionary breakfast cereals.	DAA	Noted.
International examples show prominence given to vitamin D by cereal manufacturers. Suggests manufacturers believe vitamin D is important to consumers and may influence their choices.	OPC	Noted. FSANZ has also been informed that overseas manufacturers target children's cereals as these are the population group at greatest risk of vitamin D deficiency and who gain the most benefit from added vitamin D.
Fortification may mislead consumers about the nutritional quality of products	OPC	Noted. See Review Report particularly section 5. Food and other laws in Australia and New Zealand have general provisions to ensure that marketing of food products is not misleading or deceptive.
Fortified breakfast cereal can make claims if it meets the NPSC, including 'good source' claims. Allowing these claims may give a health halo and contribute to consumers having an inaccurate view of the nutritional quality of some breakfast cereals.	OPC	Noted. See Review Report, particularly sections 5 and 7. These principles were agreed when Standard 1.2.7 was considered by Ministers.

Drivers for consumption	Submitter	FSANZ response
Lack of data showing that addition of vitamin D is a major purchasing driver for less healthy breakfast cereals.	MPI	Noted.

Drivers for consumption	Submitter	FSANZ response
Even if vitamin D was a major driver for people to purchase breakfast cereals there are mechanisms available which would allow people to assess which vitamin D fortified breakfast cereals were more or less healthy.	MPI	Noted.
There is no evidence to show that sales of non-compliant cereals would decrease or switching would occur should vitamin D fortification only be permitted in NPSC compliant cereals, but rather the likely consequence would be that those consuming non-compliant cereals would just miss out on supplementation with vitamin D	Kellogg	Noted. See Review Report, particularly section 6.
Concern that fortification of less healthy breakfast cereals may contribute to increased consumption of foods not in line with the Australian Dietary Guidelines.	OPC	Noted.
The available evidence does not support a conclusion that the influence of vitamin D fortification on consumption of breakfast cereal products will be minimal. The studies showed varying results, and there are shortcomings in the evidence base.	OPC	Noted. See Review Report, particularly sections 5 and 6.
Benefits that consumers attribute to added vitamins and mineral are general, not specific and in relation to children's healthy growth.	Nestlé	Noted. See Review Report, particularly section 5.
Consumers react more favourably to breakfast cereals communicating a health benefit linked to vitamin D and calcium, rather than just a presence claims. Since all products carrying a health claim must meet the NPSC, it appears that restricting permission for addition of vitamin D only to breakfast cereal passing nutrient profiling criteria is not necessary since content claims are not overly appealing to consumers, according to this research.	Nestlé, GLNC	Noted. See Review Report, particularly section 5.
Consumer research indicates price and taste are the strongest drivers of purchase intent suggesting fortification of ready to eat breakfast cereals is not a key driver of purchase intent for most consumers.	GLNC	Noted.
Focus groups conducted by GLNC indicate the key nutrient consumers look for in breakfast cereal is fibre	GLNC	Noted.

Drivers for consumption	Submitter	FSANZ response
Vitamin fortification has little effect on product purchase. To use a qualification filter for fortification will only serve to nutritionally disadvantage those consumers who consume 'disqualified' cereals. This then diminishes the intended public health benefit.	AFGC	Noted. See Review Report, particularly sections 5 and 6.
The application of an NPSC filter as part of a fortification permission will thus work counter to the intended public health outcome and should for this reason not be further considered.	AFGC	Noted.

Appropriate tool to restrict fortification	Submitter	FSANZ response
Prefer more strict criteria than the NPSC to be applied, as this would exclude more cereals.	Tasmania, WA, OPC	Noted. The clarification statement outlined that FSANZ should use recognised nutrient profile tools. The NPSC is considered the most practical recognised nutrient profile tools available in the current circumstances to fulfil this clarification statement.
Because the NPSC is already in the Code it is a practical approach	Tasmania, WA	Noted.
The NPSC is not an appropriate tool to apply to fortification decisions.	NZFGC	Noted.
NPSC is an appropriate tool	MPI	Noted.
If the decision is made to apply a nutrient profiling tool then the NPSC is the most logical tool to use.	Sanitarium	Noted.
The NPSC does not achieve the Forum's aim of identifying foods that are high in salt, sugar or fat or that have little or no nutritional value.	OPC	Noted. See Review Report, particularly section 6. The NPSC fulfilled the requirements outlined in the clarification statement to the Policy Guideline.
NPSC for fortification is an extension of its original purpose but do not see a problem with this extension	OPC	Noted. See responses above.
The NPSC was adapted from the UK for use in Australia for the purpose of determining foods that provided adequate nutrients to be able to make health claims, not for deciding whether foods are suitable vehicles for fortification	DAA	Noted. See responses above. The NPSC has been used as a practical approach in this instance. No assessment has been undertaken on the suitability of the NPSC for future fortification permissions.

Appropriate tool to restrict fortification	Submitter	FSANZ response
The NPSC was designed as a label claims policy for links between a nutrient and a health effect, it was not designed, nor has it ever been used as a mechanism to judge nutrient fortification. The inappropriateness of such use in this particular case is especially evident in that the NPSC makes no assessment of the vitamin status of foods, and so cannot by its nature be an effective tool for assessing the population impact or appropriateness of vitamin D fortification. The proposed tool and its task are mismatched.	AFGC	Noted. See responses above. FSANZ acknowledges that applying the NPSC to fortification permissions is an extension to its originally intended use.
The NPSC was developed to determine eligibility for health claims beyond nutrition content claims to be made. The NPSC was not intended to be applied in this manner. It introduces a precedent for future fortification practice and there is not enough evidence to support this application to permissions to fortify. This introduces inconsistency across the food supply which cannot be adequately explained by scientific evidence.	Kellogg, NZFGC	Noted. See responses above. FSANZ acknowledges that applying the NPSC to fortification permissions is an extension to its originally intended use.
Nutrient profiling is an insufficient basis to adequately assess public health risk in food regulation	Deakin University	Noted.
The principle of skewing fortification base on single nutrients using a tool that may not be appropriately assessing the healthfulness of a food category when the same tool was rejected for applying the HSR, a system intended to reflect healthfulness.	NZFGC	Noted.

Inconsistency with other fortification permissions	Submitter	FSANZ response
Existing permissions should not be used as a reason to allow fortification with additional vitamins and minerals. Each fortification permission should be considered on its own. FSANZ should assume that a product has no other voluntarily added vitamins or minerals. FSANZ cannot know which vitamin and minerals manufacturers have chosen to add to each existing and future breakfast cereal.	OPC	Noted. Voluntary addition of vitamin D to breakfast cereal has been assessed and reviewed according to the requirements of the FSANZ Act, including using the best available scientific evidence.

Inconsistency with other fortification permissions	Submitter	FSANZ response
Domestically breakfast cereal is permitted to add a number of other vitamins and minerals without passing NPSC. Applying the NPSC makes an exception by imposing nutrient profiling on one nutrient when other nutrients can already be added without nutrient profiling criteria. Introducing criteria for vitamin D is inconsistent with these permissions and creates inequity in the 15% of breakfast cereals that do not meet the NPSC.	Kellogg Nestlé, GLNC, MPI, DAA	Noted. See Review Report, particularly section 6.
A wide variety of other foods are currently eligible for fortification irrespective of their nutrient profile; yet breakfast cereals have established evidence for nutrition and health benefits. There are no other food categories where the NPSC is applied to fortification permissions	Kellogg	Noted. See Review Report, particularly sections 4 and 6.
Internationally, permission has been given to add vitamin D and other vitamins and minerals to breakfast cereal without requiring these products to pass a nutrient profiling criterion. Not applying the NPSC is consistent with international regulation	Nestlé, GLNC	Noted. See responses above and section 6.2.2 of the Review Report.

Impact on Industry of applying the NPSC	Submitter	FSANZ response
Applying the NPSC to fortification of breakfast cereal with vitamin D results in fewer cereals that could be fortified.	Sanitarium, AFGC	Noted. See Review Report, particularly section 6. FSANZ has revised the dietary model assumptions to exclude 15% of the breakfast cereal market from the vitamin D permission.
The excluded 15% of the cereal market are provided with a reformulation incentive in order to gain access to the vitamin D permission.	NSW	Noted.
Effect of applying the NPSC to voluntary permissions to add vitamin D as a driver for reformulation is unknown.	NZFGC	Noted. See Review Report, particularly section 6.
Premix concerns from industry are valid, but cereal manufacturers are not required to use the fortification permissions, so there is no need for manufacturers to incur costs.	Tasmania	Noted. See response above and section 6 of the Review Report.
Manufacturers can choose not to fortify which would improve efficiency and cost	PHAA	Noted. See response above and section 6 of the Review Report. FSANZ modelling has assumed a 30% market uptake of the vitamin D fortification permission.

Impact on Industry of applying the NPSC	Submitter	FSANZ response
No impact of restricting permission to add vitamin D to cereals that meet NPSC, because all our cereals already meet NPSC	Nestlé	Noted.
Applying the NPSC to permission to fortify with vitamin D reduces manufacturer's flexibility and consumer choice and increases manufacturing complexity, restricts innovation and introduces costs that are likely to be passed onto the consumer.	Kellogg, NZFGC	Noted. See response above and sections 6 and 9.1.1 of the Review Report.
Applying the NPSC to vitamin D fortification of breakfast cereal would increase the cost of importing certain breakfast cereals as a specific production run with a modified fortification profile would be required.	Kellogg	Noted. See response above and section 9.1.1 of the Review report.
Companies would need to source premixes containing vitamin D or premix without vitamin D, adding cost due to the smaller volumes of each that would be purchased vs a large volume of one premix	Kellogg, GLNC	Noted. See response above and sections 6 and 9.1.1 of the Review Report.
At a manufacturing level, the requirement would require 2 different premixes to be run; for lines to be cleaned to ensure no 'accidental inclusion' of vitamin D in cereals that were not permitted to contain vitamin D, and additional training for production operators to ensure they were accurately adding the correct pre-mix to the correct breakfast cereal. Increased the risk of product recalls (due to incorrect labelling vs a health and safety risk) may increase due to accidental use of the wrong pre-mix.	Kellogg	Noted. See response above and sections 6 and 9.1.1 of the Review Report.
This adds significant complexity to the supply chain for breakfast cereals as the majority of breakfast cereal contain the same type and amount of vitamins and minerals. By segmenting cereals which can contain vitamin D this adds complexity at the procurement and manufacturing level.	Kellogg	Noted. See response above and sections 6 and 9.1.1 of the Review Report.
Cost increases would need to be passed on to consumers potentially making it more expensive to access core grain foods that area recommended by the Dietary Guidelines. This increase in cost would be for all breakfast cereals.	GLNC	Noted.

Impact on industry of permitting vitamin D to all breakfast cereals	Submitter	FSANZ response
Breakfast cereal manufactures could use a global vitamin and mineral premix rather than requesting a premix that has vitamin D removed – this will help to reduce the cost of the premix. These impacts are diminished if permissions were to be restricted by qualifying criteria	Kellogg, Nestlé, GLNC, AFGC	Noted.
Permitting fortification of all breakfast cereals provide industry with the opportunity to fortify a wide range of cereals that meet the needs of people of different ages and socio economic backgrounds, hence providing a wider range of vitamin D fortified cereals.	Sanitarium	Noted.
Consistency across markets for fortification assists with reducing complexity and cost. Increasing choice for the consumer through import, will be made more difficult if specific permission apply to some products over others. Increase the number of products that would be able to be imported into Australia.	Kellogg	Noted. See Review Report particularly section 6.
Permitting vitamin D fortification in all breakfast cereal would make domestic standards consistent with international standards and thereby facilitate trade as vitamin D fortification is permitted in USA, Canada and UK breakfast cereal	GLNC, NZFGC, Kellogg	Noted. See Review Report particularly sections 6 and 9.

Drafting	Submitter	FSANZ response
If the NPSC is applied to fortification of breakfast cereal with vitamin D, consideration should be given to a draft variation that requires the same relevant additional labelling requirements to be met as outlined in Division 7 of Standard 1.2.7. This will assist enforcement agencies to determine if a given breakfast cereal meets the NPSC as all relevant details will be provided on the label.	MPI	Noted. See Review Report, particularly section 7 and approved draft variation (as amended) at Attachment A.

Future / precedent setting	Submitter	FSANZ response
The application of the NPSC more widely across the food supply to fortification decisions already made, and to proposals in the future raises concerns. There may well be flow on effects as a result affecting a much broader range of applications. Ingredient suppliers will by-pass the region as unworthy of investment because: • the costs associated with making applications and • outcomes can be and are shown to be perverse. This may have a significant and negative impact on food choices, innovation and development and ultimately on the economics of manufacturing for Australia and New Zealand.	NZFGC	Noted, This review related only to the voluntary fortification of breakfast cereal with vitamin D. However, FSANZ understands that the clarification statement, clarifies the Policy Guideline Fortification of Food with vitamins and minerals more broadly, and will therefore be considered as part of the assessment in future fortification applications or proposals. Noted.
It is not clear if proposal A1090 extends to foods already fortified with vitamins and minerals that are not meeting the NPSC.	Kellogg	Noted. See response above.
Concern that fortification of breakfast cereals may be extended similar foods (precedent setting)	Tasmania	Some of the mentioned foods in this submission are already permitted fortification e.g. breakfast drinks already permitted to contain 5 µg vitamin D per serve. FSANZ assesses each fortification on its merit. See response above.

Principles for fortification	Submitter	FSANZ response
Fortification should only be permitted where the demonstrated public health benefit outweighs the risk of increased consumption of foods not in line with ADG.	OPC	Noted. See Review Report, particularly sections 4, 5 and 6. FSANZ has had regard to the Policy Guideline which aligns with Codex principles: *General Principles for the Addition of Essential Nutrients to Foods* (CAC/GL 9-1987)

Submitter references for consumer response	Submitter	
Harris, JL Nutrition-related claims on children's cereals: what do they mean to parents and do they influence willingness to buy?	Vic	Noted. See Review Report, particularly section 5.3. The Harris et al. 2011 article was included in the original nutrition content claims literature review from 2012.
Sutterlin, B and Seigrist M, Simply adding the word 'fruit makes sugar healthier: The misleading effect of symbolic information on the perceived healthiness of food.	Tas, WA	Noted. See Review Report and SD4. The article has been included in the update of the nutrition content claims literature review.

Submitter references for consumer response	Submitter	
Faulkner, G et al, Perceived 'healthiness' of foods can influence consumers estimations of energy density and appropriate portion size.	WA	Noted. See Review Report and SD4. The article did not meet the inclusion criteria for the update of the nutrition content claims literature review.

The following tables document issues that were raised in during 2016 public consultation that are outside the scope of the review, and as such, FSANZ has not provided a response.

Out of scope: Mandatory fortification	Submitter
If this Application was motivated by public health concerns, and aimed to address this public health concern then mandatory fortification principles should have been applied, rather than leave the intervention to the discretion of the manufacturer.	Tasmania, CCA, Deakin University
If future mandatory fortification of vitamin D is warranted this Application may complicate future proposal. Mandatory fortification of milk would be a more strategic and effective way to manage vitamin D deficiency through fortification	Tasmania
Vitamin D (insufficiency) prevalence in some population groups is not best dealt with by voluntary fortification of a food that is not the most appropriate vehicle and is unlikely to be consumed by those who need it most.	PHAA
Fortification should be among a suite of potential strategies considered as a way of addressing the specific nutrient deficiency, not the only strategy for addressing the deficiency.	CCA

Out of scope: Comment on the process	Submitter
This regulatory change should be reassessed by OBPR.	NZFGC
Concerned at the potential perversion of the evidence-based standards setting system that can be amended at will by Ministers without consultation. Appreciate that this is beyond the scope of FSANZ to address but it is an important precursor to comments	NZFGC
Considers that the clarification represents a significant extension and revision of current policy and regulatory practice, and is concerned that such a policy variation however described was developed without due process. Should the Council wish to change fortification policy, it must do so in accordance with the COAG policy development criteria including a full assessment of the costs and benefits, and a full analysis of regulatory and non-regulatory options. This process has not taken place in relation to the announced 'clarification' and its absence means that the clarification may not have taken in to consideration possible adverse impacts or perverse outcomes that might otherwise have come to light.	AFGC
Food modelling systems are designed to determine dietary patterns for health, foods limited to meet guidelines for weight do not automatically become 'discretionary' food items	Kellogg
The discretionary sugar targets defined in the AHS study based on the dietary modelling from the AGHE have been taken out of the context under which they were derived.	Kellogg

Out of scope: extension beyond this Application	Submitter
The consultation paper fails to identify benefits of applying compositional criteria beyond this Application.	Tasmania
Food fortification and the nutrition and health claims food standards are contributing to dietary imbalances because the standards are being exploited for the benefit of producing and marketing discretionary foods	Deakin University
FSANZ needs to do more to use its authority to promote a healthy and sustainable food environment and to help protect public health against diet-related non-communicable disease.	Deakin University
FSANZ has overlooked public health risks associated with dietary imbalances as reflected in Dietary Guideline recommendations and instead limited its analysis to a reductionist paradigm informed by nutrient scoring	Deakin University