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Approval Report – Proposal P1038

Vitamin & Mineral Claims & Sodium Claims about Food containing Alcohol

Food Standards Australia New Zealand (FSANZ) has assessed a proposal prepared by FSANZ to address an inconsistency in the conditions for vitamin and mineral claims between current Standards 1.2.7 – Nutrition, Health and Related Claims and 1.3.2 – Vitamins and Minerals and to permit nutrition content claims about salt and sodium in relation to foods (excluding beverages) containing more than 1.15% alcohol by volume (Standard 1.2.7).

On 29 June 2015, FSANZ sought submissions on draft variations and published an associated report. FSANZ received six submissions.

FSANZ approved the draft variations on 17 September 2015. The Australia and New Zealand Ministerial Forum on Food Regulation¹ (Forum) was notified of FSANZ's decision on 1 October 2015.

This Report is provided pursuant to paragraph 63(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

¹ convening as the Australia and New Zealand Food Regulation Ministerial Council

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Executive summary

Standard 1.2.7 – Nutrition, Health and Related Claims, which regulates nutrition content and health claims, was included in the current *Australia New Zealand Food Standards Code* (Code) on 18 January 2013. This Proposal was prepared to consider two issues that have been brought to the attention of FSANZ since the Standard was gazetted.

A revision of the Code via Proposal P1025 – Code Revision, will replace the existing Code on 1 March 2016. FSANZ has therefore provided draft amendments to both the current and the revised Code, to implement the amendments made by this Proposal.

FSANZ released a call for submissions on proposed draft variations on 29 June 2015. All submitters supported the proposed draft variation.

FSANZ has finalised its consideration of this Proposal, having considered all relevant matters, and has decided to amend Standard 1.2.7 in the current Code and Standard 1.2.7 and Schedule 4 in the revised Code as outlined in the following two sections.

Vitamin and mineral claims

The gazettal of Standard 1.2.7 created a discrepancy in the conditions for nutrition content claims about vitamins and minerals between Standards 1.2.7 and 1.3.2 – Vitamins and Minerals in the current Code. This is because the minimum amounts required for making claims about vitamins and minerals (Standard 1.2.7) rely on the actual serving size of the food, whereas the maximum amount permitted to be claimed (Standard 1.3.2) is based on a prescribed reference quantity. When a food has a serving size smaller than the prescribed reference quantity, it is impossible for some vitamin and mineral claims to meet the minimum amount required to make a claim and not exceed the maximum amount permitted to be claimed.

For example, it is impossible to meet both a minimum of 1 µg and a maximum of 0.47 µg of vitamin D per 70 g serving of yoghurt:

Serving size determined by supplier:	70 g
Reference quantity specified in Standard 1.3.2:	150 g
Maximum amount of vitamin D permitted to be claimed (Standard 1.3.2):	1 µg/150 g which scales down to 0.47 µg in 70 g
Amount of vitamin D required to make a claim (Standard 1.2.7)	1 µg per 70 g serving

To address this discrepancy, FSANZ has approved an amendment to the general claim conditions in the Code to permit claims about vitamin and mineral content to be based on the prescribed reference quantity, but only if the maximum claimable amount is less than the minimum amount required to make a claim (due to the serving size specified by the food supplier). This amendment means that vitamin and mineral content claims about foods fortified with vitamins or minerals that are affected by the discrepancy will continue to be permitted as they were before Standard 1.2.7 was originally gazetted. The proposed amendment will not apply to the conditions for claims using a specific descriptor such as *good source* or *high*.

The approved amendment will also not apply to other vitamin and mineral content claims (including on the same food), where the maximum claimable amount is more than the minimum amount required to make a claim, i.e. for these claims, the minimum amount required to make the claim would remain on a per serving basis.

Sodium claims about food containing alcohol

When Standard 1.2.7 in the current Code becomes mandatory on 18 January 2016, nutrition content claims about sodium and salt in relation to food containing more than 1.15% alcohol by volume (including beverages) will be prohibited. Until then, however, under the transitional arrangements for Standard 1.2.7, nutrition content claims about sodium and salt content in relation to such foods are permitted.

Some foods containing alcohol, particularly soy sauces, are currently marketed with nutrition content claims about sodium or salt (usually *reduced sodium/salt*) in both Australia and New Zealand under the regulatory arrangements for claims in place before gazettal of Standard 1.2.7. Submitters on P1035 – Gluten Claims about Foods containing Alcohol, requested that in addition to permitting gluten claims, sodium and salt content claims should be permitted on foods containing alcohol. Of particular concern was soy sauce, as some fermented soy sauce products containing more than 1.15% alcohol by volume currently make sodium or salt claims.

FSANZ has approved amendments to the Code so that nutrition content claims about sodium and salt in relation to food (but not beverages) containing more than 1.15% alcohol by volume continue to be permitted after January 2016. This will enable suppliers to continue to alert consumers to *reduced* or *low sodium/salt* varieties of these foods. This approach is supported by national dietary guidelines, which recommend limiting intake of foods containing added salt and choosing lower/low sodium options.

The prohibition of nutrition content claims about sodium or salt in relation to beverages containing more than 1.15% alcohol by volume, and health claims about all foods containing more than 1.15% alcohol by volume (including beverages), will remain in the Code in accordance with the *Policy Guideline on Nutrition, Health and Related Claims*².

² The Policy Guideline is available at: <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx>

1 Introduction

This Proposal has been prepared to consider the following two issues associated with the gazettal of Standard 1.2.7 – Nutrition, Health and Related Claims in the *Australia New Zealand Food Standards Code* (Code):

- a discrepancy in the conditions for vitamin and mineral content claims about foods fortified with vitamins or minerals, between current Standards 1.2.7 and 1.3.2 – Vitamins and Minerals (Standard 1.3.2 and Schedules 4 and 17 in the revised Code)
- permission for nutrition content claims about sodium and salt in relation to foods containing more than 1.15% alcohol by volume.

Standard 1.2.7 in the current Code (Standard 1.2.7 and Schedule 4 in the revised Code) sets out the claims that can be made on labels or in advertisements about the nutritional content of food (described as nutrition content claims) or the relationship between a food or a property of food and a health effect (described as health claims). Standard 1.2.7 was developed under Proposal P293 – Nutrition, Health & Related Claims. It was gazetted in January 2013 and will take full effect when the transition period ends in January 2016.

1.1 Procedure for assessment

The Proposal was assessed under the General Procedure.

1.2 Decision

The draft variations as proposed following assessment were approved with amendments to reflect the amendments made to Standard 1.2.7 by Proposal P1035 – Gluten Claims about Foods containing Alcohol. The variation to the current Code takes effect on gazettal. The approved draft variation and related explanatory statement are at Attachment A.

A revision of the Code via Proposal P1025 – Code Revision, will replace the current Code on 1 March 2016. The draft variation to the revised Code and related explanatory statement are at Attachment B. The variation takes effect on 1 March 2016.

An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislative Instruments.

The draft variations on which submissions were sought are at Attachments C and D.

2 Vitamin and mineral nutrition content claims

2.1 The current Standard

Standard 1.2.7 in the current Code (Standard 1.2.7 and Schedule 4 in the revised Code) describe the conditions under which nutrition content claims can be made, including general claim conditions for the minimum amount of a vitamin or mineral required in a serving of food to make a nutrition content claim (e.g. *source* or *contains* type claims) i.e. a serving of the food must contain at least 10% of the regulatory RDI (Recommended Dietary Intake) or ESADDI (Estimated Safe and Adequate Daily Dietary Intake)³ for that vitamin or mineral.

³ The relevant regulatory RDIs and ESADDIs are prescribed in the current Code in Standard 1.1.1 – Preliminary Provisions – Application, Interpretation and General Prohibitions (Schedule 1 in the revised Code).

The serving size is determined by the supplier of the food.

For health claims about vitamins and minerals that are pre-approved in the Code, the food must meet the general claim conditions for making a nutrition content claim about the vitamin or mineral that is the subject of the claim (as outlined above).

For nutrition content claims that use a descriptor to describe the level of the vitamin or mineral in the food, e.g. *good source*, a serving of the food must contain no less than 25% of the regulatory RDI or ESADDI for that vitamin or mineral. The conditions for *good source* claims were not under consideration in this Proposal as the discrepancy is not expected to occur in relation to these kinds of claims.

Standard 1.3.2 in the current Code (Standard 1.3.2 and Schedule 17 in the revised Code) regulates the addition of vitamins and minerals to foods. For vitamins and minerals that are permitted to be added to food according to this Standard, the Standard also sets the maximum amount of that vitamin or mineral that can be claimed, per *reference quantity* of the food (ranging from 10–50% of the regulatory RDI)⁴. Reference quantities are prescribed in the Code, for example, the prescribed reference quantity for yoghurt is 150 g.

There are also permissions in Part 2.9 (Special Purpose Foods) in the Code for certain foods to or one-day quantities rather than prescribed reference quantities and were therefore not considered in this Proposal. contain added vitamins and minerals. The claim conditions for these foods are prescribed in Part 2.9 in the current Code (Part 2.9 and related Schedules in the revised Code) and are based on serving.

2.2 Reasons for preparing the Proposal

The minimum amount required to make a nutrition content claim was previously set at 10% regulatory RDI or ESADDI per **reference quantity**, but was changed to 10% regulatory RDI or ESADDI per **serving** when Standard 1.2.7 was gazetted. As outlined above, the maximum amount of a vitamin or mineral that can be claimed is based on a **reference quantity**. For foods fortified with vitamins or minerals according to permissions in Standard 1.3.2 in the current Code (Standard 1.3.2 and Schedule 17 in the revised Code), the reference quantity is prescribed and for other foods, the reference quantity is a 'normal serving'. The change from a reference quantity basis to a per serving basis in Standard 1.2.7 in the current Code (Schedule 4 in the revised Code) therefore only affects these fortified foods. The intended effect of the amendment was to prevent nutrition content claims about vitamins or minerals being made on foods containing less than 10% regulatory RDI or ESADDI per serving.

Since gazettal of Standard 1.2.7, FSANZ has been advised that, with the change from a reference quantity to a per serving basis, it is impossible for some vitamin and mineral claims to meet the minimum amount required to make a nutrition content claim and not exceed the maximum claimable amount in Standard 1.3.2 in the current and revised Codes. This can sometimes occur for fortified foods where the serving size specified by the supplier is smaller than the prescribed reference quantity. This is because the minimum amounts required for making claims about vitamins and minerals rely on the serving size of the food, whereas the maximum amounts permitted to be claimed are based on prescribed reference quantities.

⁴ If a vitamin or mineral has been added to a food, a claim must not be made that the food contains that vitamin or mineral, both added or naturally present, in greater proportions than the specified maximum claim per reference quantity of the food (Standard 1.3.2, clause 4 in the current Code and Section 1.3.2—4 in the revised Code). Section S17—4 in the revised Code specifies the actual maximum claim per reference quantity.

Dairy Australia has provided an example of the problem as follows (current Code).

<i>Yoghurt fortified with vitamin D</i>	
Serving size determined by supplier:	70 g
Reference quantity for yoghurt specified in Standard 1.3.2:	150 g
Maximum amount of vitamin D permitted to be claimed (10% RDI per reference quantity) (Standard 1.3.2):	1 µg/150 g which scales down to 0.47 µg in 70 g
Amount of vitamin D required to make a claim (10% RDI per serving) (Standard 1.2.7):	1 µg per 70 g serving
It is impossible to meet both a minimum of 1 µg and a maximum of 0.47 µg per serving.	

2.3 Summary of the findings

2.3.1 Summary of issues raised in submissions

FSANZ received six submissions in total. All six submitters supported the draft variation. A summary of issues raised by submitters and the FSANZ responses are provided in Table 1 below.

Table 1: Summary of issues

Issue	Raised by	FSANZ response
The amendments should be a temporary solution, with a review after two years to see what effect the changes are having in the market place.	Food Technology Association of Australia	The Policy Guideline on Nutrition, Health and Related Claims ⁵ foreshadows a review of the nutrition, health and related claims system two years following the implementation of the Standard. The amendments made by this Proposal will be included in that review.
Mandatory minimum serve sizes may need to be revisited to prevent the abuse that can be created. A full impact statement should be provided for any further changes to serve sizes/reference quantities. The proposal highlights need for standardised serve sizes.	Food Technology Association of Australia Department of Health & Human Services and Economic Development, Jobs Transport & Resources, Victoria	FSANZ considered prescribing serving sizes under P293 and decided not to proceed with this option. It was noted that the serving size is required to be declared in the nutrition information panel and it should not be misleading.
Understand the proposed amendment would not apply to other vitamin and mineral content claims (including on the same food), where the maximum claimable amount is more than the minimum required to make the claim.	Dietitians Association of Australia	This is correct. The exemption from the general claim conditions (based on a serving of the food) only applies to a particular vitamin or mineral claim, if certain conditions are met.

⁵ The Policy Guideline is available at: <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx>

Issue	Raised by	FSANZ response
The proposal highlights the need to update population health intake targets from Recommended Daily Intakes (RDIs) to Nutrient Reference Values (NRVs).	Department of Health & Human Services and Economic Development, Jobs Transport & Resources, Victoria	The Australian Department of Health and the New Zealand Ministry of Health are currently conducting a joint review of the 2006 Nutrient Reference Values for Australia and New Zealand. FSANZ is awaiting further developments from that review before determining the priority for updating the regulatory Recommended Dietary Intakes in the Code.

2.3.2 Risk assessment

FSANZ has concluded that a scientific risk assessment was not required for this part of the Proposal, given the purpose and effect of the amendments. That is, they are intended to remove a discrepancy within the Code and thereby permit claims that can currently be made to continue to be made, provided certain conditions are met. The recommended amendments only make a change to the permission to make vitamin and mineral claims in limited circumstances. They do not affect permissions to fortify foods with vitamins and minerals and, as such do not directly affect intake.

2.3.3 Claims affected

FSANZ considers that the number of claims likely to be affected by the discrepancy in conditions for vitamin and mineral content claims about fortified foods between the current Standards 1.2.7 and 1.3.2 (Standard 1.3.2 and Schedules 4 and 17 in the revised Code) is limited, for the following reasons:

- The problem can only occur for claims about foods that are permitted to be fortified with vitamins or minerals in Standard 1.3.2 (Standard 1.3.2 and Schedule 17 in the revised Code) and when the claim is about a vitamin or mineral that has been added to the food, as these are the only claims for which a maximum claim and reference quantity are prescribed.
- The problem occurs only when foods permitted to be fortified with vitamins or minerals have:
 - a prescribed maximum claimable amount of a vitamin(s) or mineral(s)
 - a serving size (nominated by the supplier) that is smaller than the prescribed reference quantity in Standard 1.3.2 (Schedule 17 in the revised Code).
- Furthermore, the likelihood of the problem occurring depends on how low the maximum claimable amount is, i.e. it is more likely to occur for claims about vitamins and minerals with a maximum claimable amount of only 10–15% regulatory RDI, as at this amount, unless the serving size is either the same as the reference quantity (if 10% RDI) or slightly smaller (if 15% RDI), it would not be possible to meet both criteria.
- For some foods with a maximum claimable amount of only 10–15% regulatory RDI, the prescribed reference quantity is relatively small and it may not be practical or necessary for the food supplier to specify a smaller serving size. Therefore the problem will not occur.

The above points are illustrated in Table 2, which lists the vitamins and minerals with a maximum claimable amount of 10–15% regulatory RDI and the corresponding foods and reference quantities prescribed in Standard 1.3.2 in the current Code (section S17—4 in Schedule 17 in the revised Code). For example, for margarine, the only vitamins and minerals with a maximum claimable amount of 10–15% regulatory RDI are vitamins A and D and the prescribed reference quantity is 10 g. For the problem to occur, the serving size of margarine specified by the supplier would need to be less than 10 g.

Dairy Australia has informed FSANZ that currently within the dairy industry, the issue affects mainly single serve yoghurts and dairy desserts.

Table 2: Vitamins and minerals with a maximum claimable amount of 10–15% of the RDI, with corresponding foods and prescribed reference quantities

Vitamin or mineral	Food	Prescribed reference quantity
Zinc	Biscuits, cereal flours	35 g
	Breads	50 g
	Pasta	35 g (uncooked, dried)
Vitamin A	Dried milk	200 mL (after reconstitution)
	Cream and cream products (no more than 30% milkfat)	30 mL
Vitamin A, Vitamin D	Modified milks and skim milk	200 mL
	Cheese and cheese products	25 g
	Yoghurts, dairy desserts	150 g
Vitamin A, vitamin D	Butter, edible oil spreads, edible oils and margarine	10 g
Iron	Extracts of meat, vegetables or yeast and foods containing no less than 800 g/kg of these extracts	5 g
Vitamin A, vitamin D and iodine	Beverages derived from legumes	200 mL
Thiamin, riboflavin	Analogues of meat derived from legumes	100 g
Vitamin A, vitamin B12, vitamin D, folate and iodine	Analogues of yoghurt and dairy desserts derived from legumes	150 g
Vitamin A, riboflavin and vitamin B12	Analogues of ice cream derived from legumes	75 g
Vitamin A, riboflavin, vitamin B12, vitamin D and phosphorus	Analogues of cheese derived from legumes	25 g
Vitamin A, vitamin D and iodine	Beverages derived from cereals	200 mL

2.3.4 Decision

FSANZ has approved draft variations amending the general claim conditions in Standard 1.2.7 in the current Code (Schedule 4 in the revised Code) to permit claims about vitamin and mineral content to be based on the prescribed reference quantity, but only when the maximum claimable amount (Standard 1.3.2 in the current Code and Standard 1.3.2 and Schedule 17 in the revised Code) **is less** than the minimum amount required to make a claim (due to the serving size specified by the food supplier). This will be achieved by an amendment to the general claim conditions for making *source* or *contains* type claims⁶.

⁶ Column 2 in Schedule 1 of Standard 1.2.7 in the current Code and Column 2, S4—3 in Schedule 4 in the revised Code.

For these claims, this approach will retain the conditions for making vitamin and mineral claims that were in place before Standard 1.2.7 was gazetted.

The recommended amendment will also apply to health claims about vitamins and minerals that are pre-approved in the Code, when the food must meet the general claim conditions for making a nutrition content claim about the vitamin or mineral that is the subject of the health claim. The recommended amendment will not apply to other vitamin and mineral content claims (including on the same food), where the maximum claimable amount **is more** than the minimum amount required to make a claim, i.e. for these claims, the minimum amount required to make the claim would remain on a per serving basis.

EXAMPLE (current Code)

Yoghurt fortified with vitamin D and with calcium		
Serving size determined by supplier:	70 g	
Reference quantity prescribed in Standard 1.3.2:	150 g	
Regulatory RDI for calcium	800 mg	
	Vitamin D claim	Calcium claim
Current conditions		
Maximum claim permitted (Standard 1.3.2)	1 µg/reference quantity = 1 µg/150 g (scales down to 0.47 µg per 70 g)	320 mg/reference quantity = 320 mg/150g (scales down to 150 mg per 70 g)
Minimum amount required to make a claim (Standard 1.2.7)	1 µg/serving = 1 µg/70 g	80 mg/serving = 80 mg/70 g
Recommended amendment		
Maximum claim permitted (Standard 1.3.2)	Remains the same, i.e. 1 µg/150 g	Remains the same, i.e. 320 mg/150 g
Minimum amount required to make a claim (Standard 1.2.7)	As it is impossible to meet both a minimum of 1 µg and maximum of 0.47 µg per serving, the amount required to make a claim is based on a per reference quantity: 1 µg/150 g reference quantity	Remains the same (i.e. on a per serving basis), as it is possible to meet both a minimum of 80 mg and maximum of 150 mg per serving: 80 mg/70 g serving

For most claims, the current approach in Standard 1.2.7 in the current Code (where claims are based on serving size) will remain unchanged. However, in the limited cases (see section 2.3.3) where the maximum claimable amount is less than the minimum amount required to make a claim, claims will continue to be permitted as they were before Standard 1.2.7 was gazetted. This approach avoids the need to amend provisions relating to maximum claimable amounts, which were established according to principles now encapsulated in the Ministerial Policy Guideline: *Fortification of food with vitamins and minerals*⁷.

FSANZ is not recommending that the conditions for nutrition content claims using a specific descriptor such as *good source* or *high*⁸ be amended as part of this Proposal, as the discrepancy that has occurred with the other claims is not expected to occur in relation to these kinds of claims.

Submitters were supportive of the recommended approach, for the reasons outlined above.

⁷ The Policy Guideline is at <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx>

⁸ Column 4 in Schedule 1 of Standard 1.2.7 in the current Code and Column 4, S4—3 in Schedule 4 in the revised Code.

Dairy Australia noted in its submission that one of the nutrients most affected by the discrepancy is vitamin D and stated: *Whilst fortification permissions for vitamin D in dairy foods continues to be limited relative to population nutrient insufficiency/deficiency, the ability to continue to communicate the fortification of vitamin D for these products supports the ongoing fortification and consumer choice of these products, more broadly making an important contribution to improved nutrition and health outcomes.*

2.4 FSANZ Act assessment requirements

When assessing this part of the Proposal and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 59 of the FSANZ Act:

2.4.1 Section 59

2.4.1.1 Cost benefit analysis

The Office of Best Practice Regulation (OBPR) has advised FSANZ that the proposed changes are of a minor nature and that no further analysis (in the form of a Regulation Impact Statement) is required (OBPR ID 19217).

Affected parties include the following:

Industry: The draft variation will maintain the conditions for making vitamin and mineral claims that were in place before Standard 1.2.7 was gazetted, for a limited number of vitamin and mineral claims. It will benefit suppliers of certain fortified foods, as they will continue to be able to make claims about vitamins and minerals that would have otherwise been affected by the discrepancy in the conditions in the current Standards 1.2.7 and 1.3.2.

Consumers: The draft variation will enable consumers to continue to make informed choices about the vitamin and mineral content of fortified foods in the limited circumstances whereby claims would have been prohibited by the discrepancy in the conditions in the current Standards 1.2.7 and 1.3.2.

Government: The draft variation means that, in limited circumstances, nutrition content claims about vitamins and minerals will continue to be permitted as they were before Standard 1.2.7 was developed. Enforcement agencies will need to be aware of the alternative claim conditions when undertaking enforcement activities. There were no concerns raised from enforcement agencies in response to this Proposal.

2.4.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the Proposal.

2.4.1.3 Any relevant New Zealand standards

The draft variation amends a joint Australia New Zealand standard.

2.4.1.4 Any other relevant matters

See sections 2.4.2 and 2.4.3 below.

2.4.2 Subsection 18(1)

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

2.4.2.1 Protection of public health and safety

The draft variation makes a change to the permission to make vitamin and mineral claims in limited circumstances, rather than to the actual permissions to fortify with vitamins and minerals and therefore is not expected to impact on the protection of public health and safety.

2.4.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

The draft variation will permit vitamin and mineral claims to continue to be made about fortified foods if they meet specified conditions, thus enabling consumers to continue to make informed choices about the vitamin and mineral content of fortified foods.

2.4.2.3 The prevention of misleading or deceptive conduct

The change in claim conditions in the current Standard 1.2.7 from a reference quantity basis to a per serving basis was to prevent nutrition content claims about vitamins or minerals being made on foods containing less than 10% or 25% (depending on the wording of the claim) of the regulatory RDI or ESADDI per serving. It was considered that such claims could potentially be misleading as to an actual serving of the food being a *source* or *good source* respectively, of the claimed vitamin or mineral.

The draft variation in this Proposal will permit certain vitamin and mineral claims to revert back to being based on a reference quantity. FSANZ considers that this will affect a limited range of claims only (see section 2.3.3) and will allow claims that were permitted before the gazettal of Standard 1.2.7 to continue to be made. This supports the continuation of claims for foods that are permitted to be fortified with vitamins and minerals, irrespective of serving size. For claims about other vitamins and minerals not affected by the discrepancy between the two Standards, the minimum amount required to make a claim will be on a per serving basis.

2.4.3 Subsection 18(2) considerations

FSANZ has also had regard to:

- **the need for standards to be based on risk analysis using the best available scientific evidence**

FSANZ has concluded that a scientific risk analysis was not considered necessary given the purpose and effect of the recommended amendments (see section 2.3.2).

- **the promotion of consistency between domestic and international food standards**

The conditions for making nutrition content claims about vitamins and minerals are inconsistent across the European Union, Canada and the United States of America and in Codex Alimentarius. It is therefore not possible to achieve consistency with these international food standards.

- **the desirability of an efficient and internationally competitive food industry**

The draft variation is expected to have a positive effect on the efficiency and international competitiveness of the food industry, as they will permit existing claims to continue to be made.

- **the promotion of fair trading in food**

If the recommended changes are not made, the suppliers of affected foods will be disadvantaged as they will not be able to add more of the vitamin or mineral in order to meet claim requirements, while catering for a range of serving sizes. Increasing serving size in order to meet claim requirements is not always appropriate (as it may not reflect a normal serving) or may not meet the needs of consumers (e.g. small single serve yoghurts).

- **any written policy guidelines formulated by the Ministerial Council⁹**

In December 2003, the Ministerial Council released the *Policy Guideline on Nutrition, Health and Related Claims*¹⁰. The Policy Guideline sets out the policy principles underpinning the regulation of nutrition content claims (and health claims) and aims to permit claims and encourage industry to innovate, whilst ensuring consumers are not misled. These policy principles were taken into consideration while considering the recommended amendments.

The Ministerial Policy Guideline: *Fortification of food with vitamins and minerals* was also taken into consideration, as indicated in section 2.3.4.

3 Sodium claims about foods containing alcohol

3.1 The current Standard

Standard 1.2.7 in the current and revised Codes includes a general prohibition about nutrition content claims (except for claims about energy or carbohydrate content) and health claims for foods containing more than 1.15% alcohol by volume. This prohibits nutrition content claims and health claims about both sodium and salt, in relation to foods containing more than 1.15% alcohol by volume.

Standard 1.2.8 in the current and revised Codes requires that a nutrition information panel is provided on foods containing alcohol, such as soy sauce (an exemption is provided for beverages containing no less than 0.5% alcohol by volume). The average quantity of sodium is required to be declared in the panel and when a nutrition content claim about sodium is made, the average quantity of potassium must also be declared in the panel.

3.2 Reasons for preparing the proposal

When Standard 1.2.7 in the current Code becomes mandatory in January 2016, sodium and salt claims about foods that contain more than 1.15% alcohol by volume will no longer be permitted. Consumers will no longer be alerted to *reduced* or *low* sodium or salt varieties of these foods.

⁹ Now known as the Australia and New Zealand Ministerial Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council)

¹⁰ The Policy Guideline is available at: <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx>

Submitters on the call for submissions for P1035 – Gluten Claims about Foods containing Alcohol, requested that in addition to permitting gluten claims, sodium and salt claims should be permitted on foods containing alcohol. Of particular concern was soy sauce, as some fermented soy sauce products containing more than 1.15% alcohol by volume are currently marketed with sodium or salt claims (often *reduced* sodium/salt) under the regulatory arrangements for claims in place before Standard 1.2.7 was gazetted.

The prohibition of nutrition content claims (and health claims) about food containing more than 1.15% alcohol by volume was considered when Standard 1.2.7 was developed under Proposal P293. At that time, in accordance with the Policy Guideline on Nutrition, Health and Related Claims¹¹, FSANZ restricted the use of claims that attribute a health benefit on foods containing alcohol. Nutrition content claims about carbohydrate and energy were permitted to continue as they were already established in the marketplace. Although permitted, FSANZ was not aware that sodium/salt content claims in relation to food containing alcohol were in the marketplace at that time and therefore nutrition content claims about sodium and salt were inadvertently caught within the general prohibition of nutrition content claims and not specifically considered.

The prohibition of sodium and salt claims currently applies to alcoholic beverages and other foods containing more than 1.15% alcohol by volume, e.g. liqueur chocolates, essences, naturally fermented sauces such as soy sauce.

¹¹ The Policy Guideline is available at: <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx>

3.3 Summary of the findings

3.3.1 Summary of issues raised in submissions

FSANZ received six submissions in total. All submitters that commented on this issue supported the draft variation. A summary of issues raised by submitters and the FSANZ responses are provided in Table 3 below.

Table 3: Summary of issues

Issue	Raised by	FSANZ response
<p>Food businesses may wish to make nutrition content claims beyond salt and sodium about foods containing more than 1.15% ABV.</p> <p>Recommends that the variation be broadened to encompass all nutrition content claims.</p>	<p>Australian Food and Grocery Council (AFGC)</p>	<p>Noted, but to date no further claims have been identified. The scope was limited to salt and sodium claims as foods containing more than 1.15% ABV are currently marketed with these claims and the claims are consistent with national dietary guidelines.</p>
<p>Concerned that clause 3(b) of Standard 1.2.7 unintentionally prohibits claims of low alcoholic content or 'light' beers.</p>	<p>AFGC</p>	<p>Clause 3(b) of Standard 1.2.7 in the current Code (subsection 1.2.7—4(2) in the revised Code) applies to nutrition content claims; however the definition of nutrition content claim excludes claims that refer to the presence or absence of alcohol. Conditions for low alcohol claims are included in Standard 2.7.1 – Labelling of Alcoholic Beverages and Food containing Alcohol in the current and revised Codes.</p>
<p>The amendments should be a temporary solution, with a review after two years to see what effect the changes are having in the market place.</p>	<p>Food Technology Association of Australia</p>	<p>The Policy Guideline on Nutrition, Health and Related Claims¹² foreshadows a review of the nutrition, health and related claims system two years following the implementation of the Standard. The amendments made by this Proposal would be included in that review.</p>

¹² The Policy Guideline is available at: <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx>

Issue	Raised by	FSANZ response
<p>A definition of 'beverage' must be included in the revised Standard as 'food' means all foods including 'beverage', which is not separately mentioned in the definition for 'food'.</p> <p>In the proposed amendments it states '...about a food that is not a beverage'. This phrase can only be meaningful provided a definition of 'beverage' is elsewhere provided, as 'food' per se includes 'beverages' and a 'food that is not a beverage' means that a beverage is not a food and such an interpretation is circular and cannot exist.</p> <p>It is noted that particular 'soy sauces' contain alcohol and are liquid foods but would not be consumed in the same manner as many other liquid foods and therefore must somehow be distinguished in the definition of a 'beverage'.</p>	<p>Food Technology Association of Australia</p>	<p>FSANZ considers that a definition of a beverage is not required. 'The exemption applies in relation to all foods (as defined) other than the subset of foods that are beverages. The Code, together with most State and Territory laws, do not provide a definition of the term 'beverage'. Instead, they all rely on the ordinary and commonly accepted meaning of that term. The ordinary meaning of the terms does not include foods that are a sauce, such as soy sauce.'</p>

3.3.2 Risk Assessment

The Australian Dietary Guidelines recommend limiting intake of foods and drinks containing added salt and reading labels to choose lower sodium options among similar foods (National Health & Medical Research Council, 2013). These recommendations are based on the assessment that there is convincing evidence that decreasing sodium intake decreases blood pressure in normotensive adults. This conclusion has also been supported by the World Health Organization (2012). New Zealand dietary guidelines recommend preparing foods or choosing pre-prepared foods, drinks and snacks that are low in salt (Ministry of Health, 2003).

The guidelines also recommend limiting alcohol intake. One standard drink of alcohol is regarded as 10 g ethanol. In the case of a product such as soy sauce, a typical single serve sachet of 6 g (FSANZ, 2014) would provide less than 0.1 g alcohol and a tablespoon would provide around 0.2 g alcohol.

3.3.3 Risk Management

FSANZ recommends amending Standard 1.2.7 in the current and revised Codes to permit **nutrition content claims** about sodium and salt in relation to foods (not beverages) containing alcohol. Sodium and salt claims are consistent with national dietary guidelines as they assist consumers to 'choose lower sodium options' or foods that are 'low in salt'.

The permission for sodium and salt nutrition content claims will not be extended to alcoholic beverages. The prohibition on **health claims** about sodium and salt in relation to food (including beverages) containing more than 1.15% alcohol by volume in Standard 1.2.7 will also be retained. For these foods (including beverages), this maintains the approach in Standard 1.2.7, as developed under Proposal P293 (see section 3.2).

The requirements for providing a nutrition information panel on foods (not beverages) containing alcohol, including the requirement to declare potassium when a nutrition content claim about sodium is made, will remain.

The approved draft variations to Standard 1.2.7 differ from the draft variations as proposed in the assessment summary accompanying the call for submissions. Those draft variations have been amended to reflect the amendments made to Standard 1.2.7 by Proposal P1035 – Gluten Claims about Foods containing Alcohol.

3.4 FSANZ Act assessment requirements

When assessing this Proposal and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 59 of the FSANZ Act:

3.4.1 Section 59

3.4.1.1 Cost benefit analysis

The Office of Best Practice Regulation has advised FSANZ that the proposed changes are of a minor nature and that no further analysis (in the form of a Regulation Impact Statement) is required (OBPR ID 19217).

Affected parties include the following:

Industry: The draft variation will benefit suppliers of food (not including beverages) containing more than 1.15% alcohol by volume as they will continue to be permitted to make claims about *reduced* or *low* sodium or salt. There are not expected to be any costs to suppliers resulting from this Proposal. The requirement to declare potassium in the nutrition information panel when a claim about sodium or salt is made remains the same.

Consumers: The draft variation will enable consumers to continue to make informed choices about *reduced* or *low* sodium or salt in foods containing more than 1.15% alcohol by volume.

Government: There are no additional costs to government as the draft variation maintains the position before the gazettal of Standard 1.2.7. There will be no increase in enforcement costs to ensure that food containing alcohol ceases making sodium or salt content claims.

3.4.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the Proposal.

3.4.1.3 Any relevant New Zealand standards

The draft variation amends a joint Australia New Zealand standard.

3.4.1.4 Any other relevant matters

See sections 3.4.2 and 3.4.3 below.

3.4.2 Subsection 18(1)

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

3.4.2.1 Protection of public health and safety

The recommended amendment, to permit nutrition content claims about sodium or salt in relation to foods containing alcohol, but not alcoholic beverages, is consistent with this objective. The prohibition of most nutrition content and health claims about foods containing more than 1.15% alcohol by volume in Standard 1.2.7 was developed given social issues regarding the abuse of alcohol.

3.4.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

The recommended amendment will permit nutrition content claims about sodium and salt to continue to be made in relation to foods containing more than 1.15% alcohol by volume, thus enabling consumers to continue to make informed choices about *reduced* or *low* sodium or salt varieties of these foods.

3.4.2.3 The prevention of misleading or deceptive conduct

This objective is not considered relevant to the issues considered in this Proposal. Note that the conditions applying to sodium and salt nutrition content claims in Standard 1.2.7 in the current Code (Schedule 4 in the revised Code) will apply.

3.4.3 Subsection 18(2) considerations

FSANZ has also had regard to:

- **the need for standards to be based on risk analysis using the best available scientific evidence**

Scientific risk analysis appropriate for the issues being considered has been carried out.

- **the promotion of consistency between domestic and international food standards**

Nutrition content claims about sodium are generally permitted in relation to foods containing alcohol in international food standards. Permission to make such claims in Australia and New Zealand is therefore consistent with these international food standards.

- **the desirability of an efficient and internationally competitive food industry**

The draft variation is expected to have a positive effect on the efficiency and international competitiveness of the food industry, as it will permit existing claims to continue to be made.

- **the promotion of fair trading in food**

Submitters on the call for submissions for P1035 noted that the prohibition of sodium claims places naturally brewed soy sauce at a disadvantage to those that are not naturally brewed (therefore not containing alcohol), for no reason of health consequence. The recommended amendment means fermented varieties of soy sauce and similar fermented foods will continue to be subject to same conditions and permissions of the non-fermented varieties.

- **any written policy guidelines formulated by the Ministerial Council**¹³

In December 2003, the Ministerial Council released the *Policy Guideline on Nutrition, Health and Related Claims*¹⁴. The Policy Guideline sets out the policy principles underpinning the regulation of nutrition content claims (and health claims) and aims to permit claims and encourage industry to innovate, whilst ensuring consumers are not misled.

Overarching policy principles include that claims can be made providing *the eligibility criteria, including qualifying and/or disqualifying criteria (and any excluded categories of foods, such as alcohol and infant foods), are complied with; and the claim is socially responsible and does not promote irresponsible food consumption patterns.*

These policy principles have been taken into consideration whilst considering the recommended amendments, as outlined in the sections above.

4 Risk communication

4.1 Consultation

Consultation is a key part of FSANZ's standards development process. The process by which FSANZ considers Standard matters is open, accountable, consultative and transparent.

Public submissions were sought to obtain the views on the proposed variation to the Code. The call for submissions period was from 29 June to 10 August 2015. Submissions were invited via the FSANZ Notification Circular, media release and through FSANZ's social media tools and Food Standards News. Subscribers and interested parties were also notified via email.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Proposal.

A total of six submissions were received. Every submission was considered by the FSANZ Board. All comments are valued and contribute to the rigour of our assessment. A summary of the submissions and the responses to these are provided in Tables 1 and 3 above.

5 Transitional arrangements

The transition arrangements already in place for Standard 1.2.7 will apply to the amendments to the current Standard 1.2.7. The transition period for Standard 1.2.7 ends in January 2016.

FSANZ considers that no additional transitional arrangements are required for this Proposal on the basis that the draft variation will take effect before the transitional arrangements for Standard 1.2.7 end.

¹³ Now known as the Australia and New Zealand Ministerial Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council)

¹⁴ The Policy Guideline is available at: <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx>

5.1 Transitional arrangements for Code Revision

FSANZ has completed a review of the Code undertaken under Proposal P1025¹⁵ in order to improve its clarity and legal efficacy. Following approval of the revision and Ministerial consideration, the new Code will commence on 1 March 2016 (following gazettal on 10 April 2015 and registration on the Federal Register of Legislative Instruments). The current Code will also be repealed on this date. The approved variation at Attachment B varies the revised Code on 1 March 2016 to ensure that the revised Code is consistent with the current Code as amended by the variation at Attachment A.

6 References

Food Standards Australia New Zealand (2014) AUSNUT 2011–13 – Australian Food Composition Database. Canberra: FSANZ. Available at www.foodstandards.gov.au

National Health & Medical Research Council (NHMRC) (2013) Eat for health. Australian dietary guidelines. Available at https://www.nhmrc.gov.au/files/nhmrc/publications/attachments/n55_australian_dietary_guidelines_130530.pdf. Accessed 3 June 2015

Ministry of Health (2003) Food and Nutrition Guidelines for Healthy Adults: A background paper. Wellington. Ministry of Health

World Health Organization (2012) Effect of reduced sodium intake on blood pressure, renal function, blood lipids and other potential adverse effects. ISBN 978 92 4 150491 1. Available at www.who.int

Attachments

- A. Approved draft variation to the *Australia New Zealand Food Standards Code* and related Explanatory Statement
- B. Approved draft variation to the revised *Australia New Zealand Food Standards Code* and related Explanatory Statement (commencing 1 March 2016)
- C. Draft variation to the *Australia New Zealand Food Standards Code* (call for submissions)
- D. Draft variation to the revised *Australia New Zealand Food Standards Code* (commencing 1 March 2016) (call for submissions)

¹⁵ <http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1025coderev5755.aspx>

Attachment A – Approved draft variation to the *Australia New Zealand Food Standards Code*



Food Standards (P1038 – Vitamin & Mineral Claims & Sodium Claims about Food containing Alcohol) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on the date specified in clause 3 of this variation.

Dated [To be completed by Standards Management Officer]

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC **XX on XX Month 20XX**. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (P1038 – Vitamin & Mineral Claims & Sodium Claims about Food containing Alcohol) Variation*.

2 Variation to Standards in the Australia New Zealand Food Standards Code

The Schedule varies a Standard in the *Australia New Zealand Food Standards Code*.

3 Commencement

The Schedule commences on the date of gazettal.

SCHEDULE

[1] **Standard 1.2.7** is varied by

[1.1] inserting in clause 2 in alphabetical order, the following definitions

“**maximum claimable amount** means the maximum claimable amount as prescribed by clause 4 or clause 5 of Standard 1.3.2.”

“**reference quantity** means the reference quantity specified for the food in Column 2 of the Table to clause 3 of Standard 1.3.2.”

[1.2] deleting paragraph 3(b), substituting

“(b) a food that contains more than 1.15% alcohol by volume, other than a nutrition content claim about –

- i) energy content, carbohydrate content or gluten content; or
- ii) salt or sodium content about a food that is not a beverage; or”

[1.3] deleting the following from Column 2 of the entry for Vitamin or mineral (not including potassium or sodium) in Schedule 1

“

	<p>(a) the vitamin or mineral is mentioned in column 1 of the Schedule to Standard 1.1.1; and</p> <p>(b) a serving of the food contains at least 10% of the RDI or ESADDI for that vitamin or mineral; and</p> <p>(c) a claim is not for more of the particular vitamin or mineral than the maximum claimable amount as prescribed by clause 4 or clause 5 of Standard 1.3.2; and</p>		
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	(d) the food is not a food standardised by Standard 2.6.4, Standard 2.9.2, Standard 2.9.3 or Standard 2.9.4.		
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and substituting –

	<p>(a) the vitamin or mineral is mentioned in column 1 of the Schedule to Standard 1.1.1; and</p> <p>(b) a serving of the food contains at least 10% of the RDI or ESADDI for that vitamin or mineral; and</p> <p>(c) a claim is not for more of the particular vitamin or mineral than the maximum claimable amount; and</p> <p>(d) the food is not a food standardised by Standard 2.6.4, Standard 2.9.2, Standard 2.9.3 or Standard 2.9.4.</p> <p>Paragraph (b) does not apply where –</p> <p>(i) a maximum claimable amount applies in relation to the vitamin or mineral; and</p> <p>(ii) the serving size is less than the reference quantity; and</p> <p>(iii) the reference quantity contains at least 10% of the RDI or ESADDI for the vitamin or mineral; and</p> <p>(iv) the maximum claimable amount is less than 10% of the RDI or ESADDI per serving.</p>		
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Explanatory Statement

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 2 of Part 3 of the FSANZ Act specifies that the Authority may prepare a proposal for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering a proposal for the development or variation of food regulatory measures.

FSANZ prepared Proposal P1038 to address an inconsistency in the conditions for vitamin and mineral claims between Standards 1.2.7 and 1.3.2 and to permit nutrition content claims about salt and sodium in relation to foods (excluding beverages) containing more than 1.15% alcohol by volume. The Authority considered the Proposal in accordance with Division 2 of Part 3 and has approved a draft Standard.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation¹⁶, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunseting under the *Legislative Instruments Act 2003*.

2. Purpose

The Authority has approved a draft variation to rectify a discrepancy in the conditions required to make a nutrition content claim about a vitamin or mineral in food. The current conditions require a minimum of 10% of the RDI or ESADDI per serving of the food. The amended conditions will allow a minimum of 10% of the RDI or ESADDI per reference quantity of the food, if certain conditions are met.

The Authority has also approved a draft variation to Standard 1.2.7 to permit nutrition content claims about salt and sodium in relation to food (not beverages) containing more than 1.15% alcohol by volume.

3. Documents incorporated by reference

The variations to food regulatory measures do not incorporate any documents by reference.

4. Consultation

In accordance with the procedure in Division 2 of Part 3 of the FSANZ Act, the Authority's consideration of Proposal P1038 included one round of public consultation following an assessment and the preparation of a draft Standard and associated report.

¹⁶ convening as the Australia and New Zealand Food Regulation Ministerial Council

A Regulation Impact Statement was not required because the recommended variations to Standard 1.2.7 are of a minor nature.

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

6. Variation

Item [1] amends Standard 1.2.7.

Item [1.1] inserts definitions for maximum claimable amount and reference quantity into clause 2. These defined terms are then used in the amended entry for 'Vitamin or mineral (not including potassium or sodium)' in Schedule 1. The term 'maximum claimable amount' is defined to mean the maximum amount of a vitamin or mineral that can be claimed, as prescribed by clause 4 or clause 5 of Standard 1.3.2. The term 'reference quantity' is defined to mean the reference quantity specified for the food in Column 2 of the Table to clause 3 of Standard 1.3.2.

Item [1.2] amends paragraph 3(b) of Standard 1.2.7 by inserting a reference to salt or sodium content about a food that is not a beverage. The effect of the amendment is to permit nutrition content claims about salt and sodium content to be made in relation to a food (not a beverage) that contains more than 1.15% alcohol by volume. Any nutrition content claim made about the salt or sodium content of a food would have to be made in accordance with the conditions specified in clause 11 and Schedule 1 of Standard 1.2.7.

Item [1.3] amends Schedule 1 of Standard 1.2.7 by varying the general claim conditions for making a nutrition content claim for a vitamin or mineral (not including potassium or sodium).

The effect of the amendment is to provide an exemption from the general claim condition at paragraph (b) that requires a serving of the food contains at least 10% of the RDI or ESADDI for that vitamin or mineral). The exemption applies if each of the following exists:

- A maximum claimable amount is prescribed by clause 4 or clause 5 of Standard 1.3.2 for the claimed vitamin or mineral.
- A serving of the food (as specified determined by the supplier) is less than the reference quantity for the food as specified in Column 2 of the Table to clause 3 of Standard 1.3.2.
- The maximum claimable amount (per reference quantity) for the claimed vitamin or mineral is less than 10% of the RDI or ESADDI per serving.
- The reference quantity contains at least 10% of the RDI or ESADDI for the vitamin or mineral.

In other words, if the maximum claimable amount is less than the required 10% of the RDI or ESADDI per serving, a nutrition content claim may still be made if the reference quantity of the same food contains 10% of the RDI or ESADDI.

Attachment B – Approved draft variation to the revised *Australia New Zealand Food Standards Code* (commencing 1 March 2016)



Australia New Zealand Food Standards Code – Transitional Variation 2015 (P1038 – Vitamin & Mineral Claims & Sodium Claims about Food containing Alcohol)

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on the date specified in clause 2 of the variation.

Dated [To be completed by Standards Management Officer]

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX.

1 Name of instrument

This instrument is the *Australia New Zealand Food Standards Code – Transitional Variation 2015 (P1038 – Vitamin & Mineral Claims & Sodium Claims about Food containing Alcohol)*.

2 Commencement

The Schedule commences on 1 March 2016 immediately after the commencement of Standard 5.1.1 – Revocation and transitional provisions — 2014 Revision.

3 Variation of Standards

The Schedule varies a Standard and a Schedule of the *Australia New Zealand Food Standards Code*.

Schedule

[1] **Standard 1.2.7** is varied by deleting subsections 1.2.7—4(1) and (2), substituting

A *nutrition content claim or *health claim must not be made about:

- (a) kava; or
- (b) an infant formula product; or
- (c) a food that contains more than 1.15% alcohol by volume, other than a *nutrition content claim about:
 - (i) energy content, carbohydrate content or gluten content; or
 - (ii) salt or sodium content about a food that is not a beverage.

[2] **Schedule 4** is varied by

[2.1] inserting the following at the beginning of section S4—2

In this Schedule:

maximum claimable amount means the maximum claimable amount as prescribed by section 1.3.2—4 or 1.3.2—5.

reference quantity means the reference quantity specified for the food in the Table to section S17—4.

[2.2] deleting Column 2 of the entry for “Vitamin or mineral (not including potassium or sodium)” from the table to section S4—3, and substituting

- (a) The vitamin or mineral is mentioned in Column 1 of the table to section S1—2 or S1—3; and
- (b) a serving of the food contains at least 10% *RDI or *ESADDI for that vitamin or mineral; and
- (c) a claim is not for more of the particular vitamin or mineral than the amount permitted by section 1.3.2—4 or 1.3.2—5; and
- (d) the food is not any of the following:
 - (i) a formulated caffeinated beverage;
 - (ii) food for infants;
 - (iii) a formulated meal replacement;
 - (iv) a formulated

- supplementary food;
- (v) a formulated supplementary sports food.

Paragraph (b) does not apply where:

- (i) a maximum claimable amount applies in relation to the mineral or vitamin; and
- (ii) the serving size is less than the reference quantity; and
- (iii) the reference quantity contains at least 10% *RDI or *ESADDI for the vitamin or mineral; and
- (iv) the maximum claimable amount is less than 10% *RDI or *ESADDI per serving.

For food for infants, the food satisfies the condition for making a claim under subsection 2.9.2—10(2).

For a formulated meal replacement, the food meets the condition for making a claim under subsection 2.9.3—4(2).

For a formulated supplementary food, the food meets the conditions for making a claim under subsection 2.9.3—6(2).

For a formulated supplementary food for young children, the food meets the conditions for making a claim under 2.9.3—8(2).

Explanatory Statement

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 2 of Part 3 of the FSANZ Act specifies that the Authority may prepare a proposal for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering a proposal for the development or variation of food regulatory measures.

FSANZ prepared Proposal P1038 to address an inconsistency in the conditions for vitamin and mineral claims between Standards 1.2.7 and 1.3.2 and to permit nutrition content claims about salt and sodium in relation to foods (excluding beverages) containing more than 1.15% alcohol by volume. The Authority considered the Proposal in accordance with Division 2 of Part 3 and has approved a draft Standard.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation¹⁷, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunseting under the *Legislative Instruments Act 2003*.

2. Purpose

The Authority has approved a draft variation to rectify a discrepancy in the conditions required to make a nutrition content claim about a vitamin or mineral in food. The current conditions require a minimum of 10% of the RDI or ESADDI per serving of the food. The amended conditions will allow a minimum of 10% of the RDI or ESADDI per reference quantity of the food, if certain conditions are met.

The Authority has also approved a draft variation to permit nutrition content claims about salt and sodium in relation to food (not a beverage) containing more than 1.15% alcohol by volume.

3. Documents incorporated by reference

The variations to food regulatory measures do not incorporate any documents by reference.

4. Consultation

In accordance with the procedure in Division 2 of Part 3 of the FSANZ Act, the Authority's consideration of Proposal P1038 included one round of public consultation following an assessment and the preparation of a draft Standard and associated report.

¹⁷ convening as the Australia and New Zealand Food Regulation Ministerial Council

A Regulation Impact Statement was not required because the recommended variations to Standard 1.2.7 are of a minor nature.

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

6. Variation

Item [1] amends subsections 1.2.7—4 (1) and (2), by inserting a reference to salt or sodium content about a food that is not a beverage. The effect of the amendment is to add permission for nutrition content claims about salt and sodium content to be made in relation to a food (not a beverage) that contains more than 1.15% alcohol by volume.

Any nutrition content claim made about the salt or sodium content of a food would have to be made in accordance with the conditions specified in sections 1.2.7—12 and S4—3.

Item [2.1] inserts definitions for maximum claimable amount and reference quantity at the beginning of section S4—2. These defined terms are then used in the amended entry for Vitamin or mineral (not including potassium or sodium) in Schedule 4. The maximum claimable amount is the maximum amount of a vitamin or mineral that can be claimed, as prescribed by section 1.3.2—4 or 1.3.2—5. The reference quantity is the reference quantity specified for the food in the Table to S17—4.

Item [2.2] amends Schedule 4 by varying the general claim conditions for making a nutrition content claim for a vitamin or mineral (not including potassium or sodium).

The effect of the amendment is to provide an exemption from the general claim condition at paragraph (b) that requires a serving of the food contains at least 10% of the RDI or ESADDI for that vitamin or mineral. The exemption applies if each of the following exists:

- A maximum claimable amount is prescribed by section 1.3.2—4 or 1.3.2—5 of Standard 1.3.2 for the claimed vitamin or mineral.
- The serving of the food (as specified by the supplier) is less than the reference quantity for the food as specified in the Table to S17—4.
- The maximum claimable amount (per reference quantity) for the claimed vitamin or mineral is less than 10% of the RDI or ESADDI per serving.
- The reference quantity contains at least 10% of the RDI or ESADDI for the vitamin or mineral.

In other words, if the maximum claimable amount is less than the required 10% of the RDI or ESADDI per serving, a nutrition content claim may still be made if the reference quantity of the same food contains 10% of the RDI or ESADDI.

Attachment C – Draft variation to the *Australia New Zealand Food Standards Code* (call for submissions)



Food Standards (P1038 – Vitamin & Mineral Claims & Sodium Claims about Food containing Alcohol) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on the date specified in clause 3 of this variation.

Dated [To be completed by Standards Management Officer]

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC **XX on XX Month 20XX**. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (P1038 – Vitamin & Mineral Claims & Sodium Claims about Food containing Alcohol) Variation*.

2 Variation to Standards in the Australia New Zealand Food Standards Code

The Schedule varies a Standard in the *Australia New Zealand Food Standards Code*.

3 Commencement

The Schedule commences on the date of gazettal.

SCHEDULE

[1] **Standard 1.2.7** is varied by

[1.1] inserting in clause 2 in alphabetical order, the following definitions

“**maximum claimable amount** means the maximum claimable amount as prescribed by clause 4 or clause 5 of Standard 1.3.2.”

“**reference quantity** means the reference quantity specified for the food in Column 2 of the Table to clause 3 of Standard 1.3.2.”

[1.2] deleting paragraph 3(b), substituting

“(b) a food that contains more than 1.15% alcohol by volume, other than a nutrition content claim about –

- i) energy content or carbohydrate content; or
- ii) salt or sodium content about a food that is not a beverage; or”

[1.3] deleting the following from Column 2 of the entry for Vitamin or mineral (not including potassium or sodium) in Schedule 1

“

	<p>(a) the vitamin or mineral is mentioned in column 1 of the Schedule to Standard 1.1.1; and</p> <p>(b) a serving of the food contains at least 10% of the RDI or ESADDI for that vitamin or mineral; and</p> <p>(c) a claim is not for more of the particular vitamin or mineral than the maximum claimable amount as prescribed by clause 4 or clause 5 of Standard 1.3.2; and</p>		
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	(d) the food is not a food standardised by Standard 2.6.4, Standard 2.9.2, Standard 2.9.3 or Standard 2.9.4.		
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and substituting –

	<p>(a) the vitamin or mineral is mentioned in column 1 of the Schedule to Standard 1.1.1; and</p> <p>(b) a serving of the food contains at least 10% of the RDI or ESADDI for that vitamin or mineral; and</p> <p>(c) a claim is not for more of the particular vitamin or mineral than the maximum claimable amount; and</p> <p>(d) the food is not a food standardised by Standard 2.6.4, Standard 2.9.2, Standard 2.9.3 or Standard 2.9.4.</p> <p>Paragraph (b) does not apply where –</p> <p>(i) a maximum claimable amount applies in relation to the vitamin or mineral; and</p> <p>(ii) the serving size is less than the reference quantity; and</p> <p>(iii) the reference quantity contains at least 10% of the RDI or ESADDI for the vitamin or mineral; and</p> <p>(iv) the maximum claimable amount is less than 10% of the RDI or ESADDI per serving.</p>		
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Attachment D – Draft variation to the revised *Australia New Zealand Food Standards Code* (commencing 1 March 2016) (call for submissions)



***Australia New Zealand Food Standards Code* – Transitional Variation 2015 (P1038 – Vitamin & Mineral Claims & Sodium Claims about Food containing Alcohol)**

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on the date specified in clause 2 of the variation.

Dated [To be completed by Standards Management Officer]

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC **XX on XX Month 20XX**.

1 Name of instrument

This instrument is the *Australia New Zealand Food Standards Code – Transitional Variation 2015 (P1038 – Vitamin & Mineral Claims & Sodium Claims about Food Containing Alcohol)*.

2 Commencement

The Schedule commences on 1 March 2016 immediately after the commencement of Standard 5.1.1 – Revocation and transitional provisions — 2014 Revision.

3 Variation of Standards

The Schedule varies a Standard and a Schedule of the *Australia New Zealand Food Standards Code*.

Schedule

[1] **Standard 1.2.7** is varied by deleting subsections 1.2.7—4(1) and (2), substituting

A *nutrition content claim or *health claim must not be made about:

- (a) kava; or
- (b) an infant formula product; or
- (c) a food that contains more than 1.15% alcohol by volume, other than a *nutrition content claim about:
 - (i) energy content or carbohydrate content; or
 - (ii) salt or sodium content about a food that is not a beverage.

[2] **Schedule 4** is varied by

[2.1] inserting the following at the beginning of section S4—2

In this Schedule:

maximum claimable amount means the maximum claimable amount as prescribed by 1.3.2—4 or 1.3.2—5.

reference quantity means the reference quantity specified for the food in the Table to S17—4.

[2.2] deleting Column 2 of the entry for Vitamin or mineral (not including potassium or sodium) from the Table to S4—3, and substituting

- (a) The vitamin or mineral is mentioned in Column 1 of the table to section S1—2 or S1—3; and
- (b) a serving of the food contains at least 10% *RDI or *ESADDI for that vitamin or mineral; and
- (c) a claim is not for more of the particular vitamin or mineral than the amount permitted by section 1.3.2—4 or 1.3.2—5; and
- (d) the food is not any of the following:
 - (i) a formulated caffeinated beverage;

- (ii) food for infants;
- (iii) a formulated meal replacement;
- (iv) a formulated supplementary food;
- (v) a formulated supplementary sports food.

Paragraph (b) does not apply where:

- (i) a maximum claimable amount applies in relation to the mineral or vitamin; and
- (ii) the serving size is less than the reference quantity; and
- (iii) the reference quantity contains at least 10% *RDI or *ESADDI for the vitamin or mineral; and
- (iv) the maximum claimable amount is less than 10% *RDI or *ESADDI per serving.

For food for infants, the food satisfies the condition for making a claim under subsection 2.9.2—10(2).

For a formulated meal replacement, the food meets the condition for making a claim under subsection 2.9.3—4(2).

For a formulated supplementary food, the food meets the conditions for making a claim under subsection 2.9.3—6(2).

For a formulated supplementary food for young children, the food meets the conditions for making a claim under 2.9.3—8(2).