Food Reformulation:
Risk Assessment

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1. Introduction

Adjunct Professor Paul Brent, Faculty of Agriculture and Food Sciences, Risk Assessment and Regulatory Analysis Group, University of Laval, Quebec Canada; Dr Janis Baines of Food Standards Australia New Zealand (FSANZ); and representatives from the Department of Health Preventive Programs Section undertook technical risk characterisation and assessment work relating to risks identified for sodium, sugars and saturated fat reformulation targets for food. This has informed the work of the Healthy Food Partnership's Reformulation Working Group (RWG).

The work plan for the RWG outlines that the actions of the group will *optimise the nutritional profile of the food supply by increasing beneficial nutrients and core (five food group) foods and by reducing risk-associated nutrients where technically feasible to do so*. As a first step, the group determined that it was appropriate to target the three risk associated nutrients that posed the greatest problem in the Australian diet: sodium, saturated fat and sugars; and that targets to reduce these nutrients in foods would be set for the retail environment.

During the process of developing draft reformulation targets, the RWG identified certain potential risks associated with the proposed Partnership Reformulation Program (PRP), and therein the reduction of sodium, saturated fats and/or sugars in nominated food categories. The process of public consultation (16 July - 15 November 2018) also invited submissions about potential risks posed by the PRP and nutrient reduction targets. This risk assessment is structured so that for any identified potential food safety hazards and risks associated with reformulation of foods to reduce sodium, saturated fat and sugars, an assessment of the risk and a risk characterisation has been developed, and relevant conclusions for managing the risk have been suggested.

The assessment and conclusions will inform further considerations and subsequently the process undertaken by the RWG and Healthy Food Partnership's Executive Committee finalise targets for food product reformulation as part of the PRP.

The following Overarching Principles underpin this risk assessment work:

- Food safety is paramount.
- Retaining the product (reformulation, not new product development)
- Reformulation will reduce the sodium, saturated fat or sugar content per 100g/100mL
- Reformulation to be technically feasible
- Balance of reformulation risk against the public health risk of high sodium, saturated fat or sugars consumption.

2. Background

2.1 Healthy Food Partnership

In late 2015, the Department of Health established the Healthy Food Partnership with the aim of improving the dietary habits of Australians by making healthier food choices easier and more accessible, and by raising awareness of appropriate food choices and portion sizes.

The Healthy Food Partnership provides a mechanism for government, the public health sector and the food industry to cooperatively tackle obesity, encourage healthy eating and empower food manufacturers to make positive changes. The scope of work within the Healthy Food Partnership comprises several policy areas that consider portion size, food reformulation, food service environments and education.

This multifaceted approach reflects the fact that dietary choices are determined through a complex interplay of factors and thus there is not one single policy measure that can be introduced to shift populations onto a healthier dietary trajectory.

The product reformulation component undertaken by the RWG is supported by other initiatives, including the Australian Dietary Guidelines (ADGs), the Health Star Rating (HSR) system and nutrition labelling, which enable consumers to make healthy choices when purchasing and consuming food.

The Healthy Food Partnership is part of a wider public health program in Australia that aims to reduce risk factors for chronic disease. The RWG was tasked with establishing priorities for food reformulation which may help consumers achieve dietary patterns that are more consistent with the ADGs.

2.2 Reformulation

Reformulation seeks to restructure the food and drink environment and, when used in parallel with other initiatives, can lead to changes in dietary patterns for a population. For health purposes, the food environment can be restructured by making small, incremental positive changes to product formulations, sometimes referred to as ‘health by stealth’, providing consumers with a wider access to, and a larger number of, more healthful products.

For the general population, a significant proportion of daily energy intake is likely to come from manufactured foods, exemplifying that the actions of the private food sector holds tremendous potential to influence the diet of a population, in terms of scale and reach[(1)]. From an economic perspective, it has been identified as one of the most effective nutrition policy interventions, measured in disability-adjusted life years saved[(2)].

3. Risk Assessments

Food Safety Risks

3.1 Food safety risk - Sodium acts as a microbial inhibitor

Comments in submissions

- Salt is a preservative and therefore reducing the amount will mean either shorter shelf life (food spoilage), or else more artificial ingredients. There are safety concerns for cheese, shelf stable cheese, processed meat, and ham categories in particular from salt reduction. It also has a role as pathogen inhibitor.
- As a preservative, salt inhibits microbial growth in processed cheese. Any salt reduction creates significant challenges in managing microbial growth in the product. This in turn poses food safety risks.

Risk Assessment

The Australia New Zealand Food Standards Code includes requirements around food safety and food labelling, including chapter 3 Food Safety Standards (Australia only) and Chapter 4 Primary Production and Processing Standards (Australia only).

Food safety is paramount, and sodium reformulation should not be conducted if the food safety risks cannot be adequately managed. This will vary between products and processing methods. Food industry technologists will need to determine what options for sodium reduction are technically feasible for specific products while being acceptable to the individual business. The PRP provides flexibility for food industry to self-determine how the reformulation target may best be achieved, within the broader intent of the Healthy Food Partnership which is to increase the overall healthfulness of the food supply.

In determining the draft reformulation targets for sodium, the RWG considered available product data. The presence of products in each category which already meet the draft sodium targets indicated the target should be technically feasible and safe.

Food safety risks are best assessed by manufacturers for individual products. Reformulation should not be conducted at levels where product safety cannot be effectively managed.

Industry reporting on progress against the PRP should seek to identify instances of products unable to meet the target due to un-manageable food safety risk; and if the rate is high, consideration be given to reviewing those relevant category targets.

3.2 Food safety risk - Sodium reduction in bread may result in the increase in use of food additives and other artificial ingredients; and reduced shelf life

Comments in submissions

- Sodium content reduction in bread (achieved by reducing its salt content) may result in loss of taste; increase in use of food additives (MSG and other additives); and reduced shelf life that is not desirable from a health or food safety point of view and will have lower consumer acceptance. New regulations should not steer or force manufacturers towards less natural ingredients.

Risk Assessment

Salt is a common ingredient in bread and baked products and has three main technological functions: salty taste and enhancement of other flavours, anti-microbial properties such as a preservative, and functional properties. Sodium salts other than the chloride form are also found in some baked products (e.g. baking powder), but not necessarily in bread itself. In bread, the main technological functions of salt are the development of gluten structures in the mixing of bread and other fermented products; inhibition of bakers' yeast in the fermentation of bread doughs allowing the formation of good crumb and crust properties; and control of water activity in the baked product. If salt levels are too low the dough becomes less elastic and sticky, initially the dough is firmer but with ongoing mixing becomes less stable. As a preservative salt influences water activity, assisting in preventing the emergence of pathogens such as *Listeria monocytogenes* or *Clostridium botulinum* in combination with other microbial agents where used. The shelf life of bread may be affected by salt reduction, though it depends on the extent of the reduction[3-5].

In Australia, bread makes a significant contribution to total sodium intakes, so as part of a public health initiative to reduce sodium intakes from the diet it was selected as a target food for reformulation to reduce salt and hence sodium content.

Contribution of bread to total sodium intakes

From the 2011-13 Australian Health Survey (AHS), the average daily intake of sodium from food for the general population was just over 2,404 mg excluding the 'discretionary salt' added by consumers in home prepared foods or 'at the table' (64% of Australians reported that they add salt very often or occasionally either during meal preparation or at the table) [6]. For the general population, sodium consumption was significantly higher among males than females across the age groups and peaked among males aged 14-18 years and 19-30 years whose average consumption was 3,117 mg/day and 3,120 mg/day respectively (equivalent to 8 grams of salt per day). One-quarter (25%) of sodium came from Cereal-based products and dishes (mainly from the mixed dishes where cereal is the major ingredient), while 18% came from Cereal and cereal products (mainly bread) and 18% came from Meat and poultry (mainly processed meat and mixed dishes)[6].

Similar information was reported from the AHS for the Aboriginal and Torres Strait Islander populations with an average sodium intake of from food of 2,379 mg/day, with approximately one-quarter (23%) from Cereal-based products and dishes (mainly from the mixed dishes where cereal is the major ingredient), 19% from Cereal and cereal products (mainly bread) and a quarter (23%) from Meat and poultry (mainly processed meat and mixed dishes)[7].

The general adult population had mean usual sodium intakes that exceeded the Suggested dietary target (SDT) to reduce chronic diseases of 2000 mg sodium/day set in 2017[8]. The new target of 2000 mg sodium/day is deemed to be more realistic than the previous SDT of 1600 mg/day as it represents a total diet that meets all nutritional requirements, given the current food supply.

Technical options for reducing the sodium content of bread

There are several options for reducing the salt content of bread whilst retaining the desirable properties of bread and bread dough. Although the salt content of bread can be reduced by a certain amount with no further changes in ingredients, in some products it may be necessary to use alternative food additives to partially replace sodium chloride[3,4]. Replacement of some of the sodium chloride with potassium chloride (10-15%), use of magnesium salt mixtures, encapsulating salt in the product (up to 50% reduction possible) and use of organic acids to assist in preservation functions have been suggested as possible options. Use of alternative food additives may change the proportion of additives in the final food, but as sodium is currently <1%

of the final food the change may not be significant when expressed as a percentage change for the whole product. In terms of loss of taste, the gradual reduction of salt levels in bread over a set time period (e.g. by 5% increments) can assist in adjusting consumers' taste perceptions, such that the change is not noticed[3].

It is important, therefore, that manufacturers have flexibility in implementing the PRP for their specific bread products. However, it is not likely to introduce new food additives to the food supply as the proposed alternatives are commonly used in other food products. All food additives, including preservatives are regulated by FSANZ. If use of an additive new to the Australian or New Zealand food supply were to be proposed as part of reformulating bread to reduce its sodium content it would need to be assessed by FSANZ prior to being permitted for use.

Reformulation targets

The proposed sodium targets for bread and flat bread are based on an assessment of the current range of products in the Australian market. One of the criteria for determining targets is based on the assumption that the target is feasible and appropriate if approximately one-third of products met the target. This assumed it would be likely that it was technically feasible for the remaining two-thirds of products to reformulate, while retaining the nature of the food product.

The proposed target for sodium in breads is a maximum of 380mg/100g, excluding value-added breads such as cheese and bacon rolls, and a maximum of 450mg/100g in flat breads. These targets are similar to those established elsewhere. For example, in New Zealand, the same targets have been set[9] and in England, the 2017 target for sodium in all bread and rolls including flat breads is an average sodium content of 360mg/100g, maximum of 450mg/100g and for value-added breads an average of 400mg/100g, maximum 450mg/100g[10]. The table below indicates potential ranges of sodium content in breads in the current Australian food supply.

	FoodTrack™ Sodium content of bread from labels **mg/100g**	**AUSNUT 2011-13 Sodium content of bread range, analysis*** **mg/100g**	**Target sodium level in bread (maximum level)** **mg/100 g**
Breads	163-876 Mean 390.50	190-650 (Excl. value-added breads)	380
Value-added breads#		650-860	
Flat breads	21-1020 Mean 509.37	71-900	450

*Toasted breads not included
Value-added breads excluded from the PRP

Data on sodium content ranges were obtained from food labels for breads and flat breads held in the FoodTrack™ database (data extracted September 2017)[11]. The FSANZ AUSNUT 2011-13 database[12] includes analytical data on sodium in breads, updated in 2013, based on bread surveys undertaken by FSANZ from 2010-2013. The sodium content ranges from these two data sources in Australia are similar.

The data in AUSNUT 2011-13 indicates the sodium content of breads ranges from 190-650mg/100g and flat breads from 71 (Ethiopian injera bread) to 900mg/100g. Sodium levels at the lower end of the range are for corn, focaccia and rye breads (190-395mg/100g), whilst levels tend to be over 380mg/100g for white bread and rolls (400-470mg/100g), wholemeal, gluten free and organic bread and rolls (470-540mg/100g) and mixed grain breads, undefined breads and rolls (540-650mg/100g). Within each category bread rolls tend to have a higher sodium content than the equivalent bread loaf. Value added breads, which are excluded from the PRP targets, have the highest sodium content range from 660—860mg sodium/100g. A higher percentage reduction in sodium content will therefore be required for most wholemeal, organic, gluten free and mixed grain breads than white breads to meet the proposed sodium content target for bread.

The 2011-13 AUSNUT values reflect the outcomes of the previous voluntary food reformulation program, the Food and Health Dialogue which included targets to reduce sodium levels in specified bread products to 400 mg sodium/100g(13). Many manufacturers participated in the program (covering approximately 80% market for bread products at that time). Sodium levels in bread were considerably reduced compared to previous levels, indicating that it was possible to make salt reductions without compromising the bread product. Sodium levels may have been further reduced since 2013.

The reduction in sodium levels proposed for bread is at the lower end of the range of sodium content of bread products already in the market place and is technically feasible to achieve without compromising food safety. Value-added bread products are excluded from the PRP because they contribute less sodium overall to Australian diets. It is also difficult for manufacturers to reduce the sodium in these products as the toppings (e.g. cheese, ham, bacon) contribute a large portion of the products sodium, though manufacturers could choose to reduce sodium levels in these products.

There is intended to be flexibility in the implementation of a voluntary sodium/salt reduction program for manufacturers for bread products within their product range as there are several technical options to reduce salt levels in bread that can be employed singly or in combination. Although the salt content of bread can be reduced a certain amount with no further changes in ingredients, in some products it may be necessary to use alternative food additives to partially replace sodium chloride. The use of alternative food additives in bread products is not likely to introduce new food additives to the food supply as they are commonly used in other food products. The potential loss of taste for sodium/salt reduced bread can be managed by an incremental decrease in salt content of bread over a period that results in consumers being unaware of the changes, but this approach requires a long lead-in time to the final deadline for reaching targets.

3.3 Food safety risk - Probiotics in dairy products

Comments in submissions

- Probiotics in dairy products may die if insufficient sugar to feed them

Risk Assessment

The United Nation's Food and Agricultural Organization and the World Health Organization define probiotics as "live organisms, which, when administered in adequate amounts, confer a health benefit on the host." Intestinal flora, or "friendly bacteria," occur naturally in the human gut. Two examples, lactobacilli and bifidobacteria, found in the human intestines, are commonly used as additives in yogurt and other foods and supplements. “Live cultures” refers to bacteria associated with foods, such as those present in fermented milk, the original source of yoghurt (14).

<u>Reformulation targets for sugar in dairy products</u>

The proposed sugars targets for yoghurt are based on an assessment of the current range of products in the Australian market. It was assumed likely that the target was technically feasible if there were existing products on the market that were at or below the proposed target. The proposed target for yoghurt (at the 2018 consultation) was a maximum of 13.5g sugar/100g.

Manufacturers have flexibility in implementing the reduced sugars targets in yoghurt, including those containing probiotics, and would need to monitor the impact of reducing sugar content on the viability of the live culture so that the nature of the product was retained. Although sugar may be used as a substrate for probiotics, most is used during the fermentation process so would not remain in the final product. The sugars target applies to the amount of sugar declared on the label for the final product.

To ensure that any given culture maintains the beneficial properties, the stock culture should be maintained by the manufacturer under appropriate conditions and be checked periodically for strain identity and probiotic properties. Viability and probiotic activity must be maintained throughout processing, handling and storage of the food product containing the probiotic and verified at the end of shelf-life, such that it is in line with declared content on the food label [14].

For a dairy product containing probiotics, manufacturers have flexibility in implementing the reduced sugars targets in yoghurt, including those containing probiotics, and would need to monitor the impact of reducing sugar content on the viability of the live culture so that the nature of the product was retained. Viability and probiotic activity must be maintained throughout processing, handling and storage of the food product containing the probiotic and verified at the end of shelf-life, such that it is in line with declared content on the food label.

Public Health Risks

3.4 Public health risk - Adverse health impact of decreased consumption of dairy, wholegrains. Inconsistent with ADG / healthy eating policies

Comments in submissions

- Cheese – if reformulation inadvertently leads to decreased consumption, negative health impact of reduced dairy consumption. “As cheese consumption is associated with a reduced risk of both coronary heart disease and stroke, we do not support the proposed cheddar cheese sodium reformulation target.”
- If reformulation were to make five food group foods less appealing, this [nutrient reformulation] is not a strategy consistent with the ADGs.
- There is an identified risk that reformulation policies targeting individual nutrients may actually legitimise, endorse or even promote the consumption of unhealthy foods. Reformulated discretionary foods may then be promoted /perceived as healthy foods despite still being a discretionary food, e.g. a no sugar sweet biscuit with added fibre powder is still a discretionary food.
- Possible adverse effects on public health due to the undermining of policies aiming to promote consumption of healthy (five food group) foods rather than unhealthy (discretionary choices) - reformulated foods are likely to achieve a higher HSR, this has the potential to undermine policies that aim to promote the increased consumption of foods that are unable to be reformulated, such as minimally processed five food group foods.

Risk Assessment

Businesses are unlikely to implement reformulation targets if the renovated product does not meet consumer acceptability testing. If products are still acceptable in the absence of any other factors, consumption is presumed to remain consistent, for the purpose of modelling the PRP. The impact of overt promotion of reformulated products as being 'lower sodium' or 'healthier' products than their original counterpart products etc. is unknown – there is obviously a market for 'low salt' products in some categories as these already are in the market and marketed thus. Product promotion is not required as part of the PRP, and anecdotal evidence suggests that 'health by stealth' and whole categories of products moving incrementally to a lower content of nutrients such as sodium, saturated fat or sugars often goes un-noticed by consumers. This approach has been particularly successful for salt/sodium reduction in Australia and elsewhere(3). The PRP provides flexibility for food industry to self-determine how the reformulation target may be achieved.

The presence of products in each category which already meet the draft sodium targets indicate the target should be technically feasible in a product that is acceptable to consumers.

It is noted that some of the public consultation submissions called for targets to be lower, such that products meeting them would achieve thresholds for sale in school canteens as amber (select carefully) foods (see 2010 *Guidelines for healthy foods and drinks supplied in school canteens*). i.e. that reformulation should push harder such that products such as pizza may be healthy enough to be sold in canteens (max 400mg sodium/100g; Amber; still a discretionary food), or that industry may already be working towards that target, so there is value in aligning with it.

While reformulation may affect the baseline or modifying points scored for nutrient content of foods in the HSR system, not all reformulation will be sufficient to alter the star rating. Companies are already reformulating products, where possible, to achieve higher star ratings. At the time of development of the PRP, the HSR is under review. The PRP cannot foresee what changes may be made to the HSR system, but a transition period would be required.

Health and nutrition awareness activities of Department of Health, including under the Healthy Food Partnership, HSR system, and Healthy Aussie Produce campaign contextualise food product choices within total diet; including promoting consumption of five food group foods, particularly fruit and vegetables.

The ADGs include *Guideline 3 Limit intake of foods containing saturated fat, added salt, added sugars and alcohol*(15). As such reducing the level of these nutrients in foods can be seen as supporting Guideline 3. Promotion of healthy diets which align with the ADGs is important; but recognising that most Australians do not necessarily eat in this way, improving the nutritional aspects of a wide range of foods is one way to improve total diet at the population level.

Ongoing nutrition and dietary intake monitoring should track any changes in consumption of five food group foods, including as components of mixed foods (e.g. casseroles).

Some mixed foods made up of core food ingredients will not be considered as discretionary, as defined in the ADG, noting these definitions were used by the ABS when flagging foods that were reported as consumed in the 2011-13 AHS as discretionary or not. There may be other products for which reformulation and reduction of risk nutrients moves them to levels such that they would no longer be classified as discretionary foods. This is consistent with the aim of helping consumers to limit their intake of foods containing saturated fat, added salt and added sugars. Further, the NHMRC is undertaking work for the Department to better classify discretionary foods, in an effort to help consumers better understand which foods are discretionary foods.

Dietary intake surveys should be used to monitor for any changes in consumption of five food group foods (reduced consumption of fish, dairy, wholegrains have been noted in submissions as points of concern, however the principle of monitoring applies to all). Ease of monitoring for these do vary and causality of any increase or decrease would be uncertain and may not be able to be specifically attributed to the PRP.

Consumer messaging about consumption patterns that align with the ADGs should continue and increase.

3.5 Public health risk - Sodium reduction in cheese may result in changes to the HSR that are not consistent with other public health messages.

Comments in submissions

- When sodium in cheese is reduced, moisture and fat levels increase and this in turn has an impact on energy content. This is neither consistent with the effort, cost or investment, nor reflective of the ADG recommendations around cheese and health.
- The HSR is currently undergoing a five year review and likely to be changes to cut off points (primarily sodium and sugar levels), which could impact PRP draft targets.

Risk Assessment

Salt (sodium chloride) is a critical ingredient in cheese products and has three main technological functions: salty taste and enhancement of other flavours, anti-microbial properties such as a preservative, and functional properties. In cheese, the main functional property of salt in cheese is to sequester the calcium in the milk protein (mainly casein), facilitate its hydration and conversion to an active emulsifier which allows the emulsification of fat and the formation of a stable homogenous end-product. It also modulates the starter cultures. Reduction of salt levels in cheese can lead to loss of homogeneity and characteristic texture and flavour of the cheese(3,16,17). Salt also prevents microbial growth in cheese, inhibiting the generation of microbial spores such as *lactobacilli*, thus limiting the growth of foodborne disease and spoilage organisms.

Technical options for reducing the sodium content of cheese

There are limited technical options for natural cheese to reduce the level of salt in cheese, as a reduction affects the flavour profile and other characteristic properties. Salt can be partially replaced by potassium chloride, however at certain levels its use introduces a bitter taste, affects homogeneity and texture (crumbliness increases) and can reduce microbial stability. The performance of potassium chloride in processed cheeses is better, so a higher proportion of potassium chloride to sodium chloride could be used and potassium emulsifiers can replace salt(3,17).

Salt reduction can also be achieved by increasing the moisture and/or reducing the fat content of cheese. However, because low-fat cheese has a higher moisture content the salt to fluid ratio is lower than in normal cheese with the same total salt content, which promotes the growth of spoilage organisms thus reducing shelf life and limiting the extent of sodium reduction in low-fat cheese(3).

Reformulation targets

The proposed sodium targets for cheese and processed cheese are based on an assessment of the current range of products in the Australian market. One of the criteria for determining targets is based on the assumption that the target is feasible and appropriate if approximately one-third of products met the target. This assumed it would be likely that it was technically feasible for the remaining two-thirds of products to reformulate, while retaining the nature of the food product.

The proposed target for sodium in cheddar type cheeses is a maximum of 710mg/100g, and the target for in processed cheese a maximum of 1270mg/100g. These targets are similar to those established elsewhere. For example, in New Zealand, the same targets have been set for these products[9]; in England, the 2017 target for sodium in cheddar type cheese is an average sodium content of 700mg/100g, maximum of 800mg/100g and for processed cheese an average of 680mg/100g, maximum 800mg/100g[10].

Reported ranges for the sodium content in cheeses from food label information derived from the FoodTrack™ database on were 500-790mg/100g for cheddar type cheeses (mean 662.25mg/100g) and 1030-1940mg/100g for processed cheeses (mean 1415.80mg/100g).

Potential impact of reducing the salt content of cheese on HSR

While reformulation may affect the baseline or modifying points scored for nutrient content of foods in the HSR system, not all reformulation will be sufficient to alter the star rating. Companies are already reformulating products, where possible, to achieve higher star ratings. At the time of development of the PRP, the HSR is under review. The PRP cannot foresee what changes may be made to the HSR system, but a transition period will be required.

In terms of other nutrient components of cheese, as salt is a minor ingredient any reductions in the amount of salt (sodium chloride) and/or increases in potassium chloride are unlikely to change the macronutrient content per 100g as sodium content is less than 1g/100g in cheddar type cheeses and less than 1.4g/100g in processed cheeses. The HSR may change if the salt content is reduced to a level that results in less sodium points being assigned.

If the macronutrient content of cheese is changed, for example the fat content is reduced, then the proportion of other significant macronutrients (protein, in this case) increases when expressed per 100 g and the HSR is more likely to change to a higher star rating (due to lower energy and fat content and higher protein content). For cheddar type and processed cheeses, the sodium content tends to be lower in the fat reduced version and may result in less HSR baseline sodium points in these products. The moisture content of reduced fat cheese is higher than regular cheese for both cheddar type and processed cheeses (see technical options above). Reducing sodium in cheese by increasing moisture levels is another option for sodium reformulation[3], but if this option were to be selected by manufacturers on its own the extent of reduction of sodium content possible would be determined by the microbial safety of the end product. The safety of cheese products offered for sale are regulated by FSANZ in Chapter 3 *Food Safety Standards* (Australia only), Standard 4.2.4 *Primary production and processing standard for dairy products* and Schedule 27 *Microbiological limits in food.*

The typical nutrient content of cheddar and processed cheese, regular and reduced fat versions is given in the table below for relevant nutrients per 100 g cheese, taken from the Australian Food Composition Database[18].

	Energy kJ/100 g	Protein g/100 g	Total fat g/100 g	Sat fat g/100g	Total sugars g/100 g	Sodium mg/100 g	Potassium mg/100 g	Moisture g/100 g
Cheddar type cheese								
Regular	1663	24.6	32.8	21.65	0.4	684	73	34
25% fat reduced	1368	28.6	23.4	15.1	0	550	110	41.7
15% fat reduced	1109	31.1	15.3	9.87	0	560	110	47.1
Processed cheese, cheddar								
Regular	1254	21.1	23.9	16.04	0.1	1420	125	48.4
15% fat reduced	1054	22.5	15.4	10.26	4.9	1171	170	52.5

Ref 18

Consistency of the sodium reformulation targets for cheese with the ADGs

The 2013 Australian Dietary Guideline 2 is to '*enjoy a wide variety of nutritious foods from the five food groups* [including] *milk, yoghurt, cheese and/or their alternatives, mostly reduced fat*'[15].

The guidelines are based on scientific evidence, which for dairy products has strengthened in recent years, noting the evidence base considered in preparing the ADGs for consuming dairy products and/or alternatives primarily comprised small, short-term studies with varied definitions of dairy foods[19], see evidence statements for dairy foods (milk, yoghurt, and cheese) and grade of evidence in table below.

Evidence statement	Grade
Consumption of at least two serves per day of dairy foods (milk, yoghurt, and cheese) is associated with reduced risk of ischemic heart disease and myocardial infarction	B
Consumption of two or more serves of dairy foods per day is associated with reduced risk of stroke	B
Consumption of three serves of low fat dairy foods is associated with reduced risk of hypertension	B
Consumption of more than one serve of dairy foods per day, especially milk, is associated with a reduced risk of colorectal cancer	B
Consumption of three or more serves of milk per day is not associated with risk of renal cell cancer	B
Consumption of three serves of any milk, cheese or yoghurt products a day is associated with reduced risk of hypertension	C
Consumption of two to four serves of dairy foods per day is associated with reduced risk of metabolic syndrome	C
Consumption of at least one and a half serves of dairy foods (milk, yoghurt, cheese) per day is associated with reduced risk of type 2 diabetes.	C
Consumption of more than one serve of milk per day is associated with reduced risk of rectal cancer.	C
Consumption of dairy products (particularly milk) is associated with improved bone mineral density.	C

Ref 19, Table 2.13

There are a range of cheese products currently available within the hard and soft cheese categories that offer different nutrient profiles to the consumer trying to follow dietary guidelines in relation to selecting products with lower fat and sodium content or for specific health reasons. As noted earlier the fat, moisture and salt content of different cheeses provide characteristic texture and flavour. Reduced fat products are also available, mainly for cheddar type and processed cheeses.

Soft cheeses like cottage cheese tend to have a lower average total fat content than cheddar cheese types, as do some of the semi-soft and hard cheeses such as fetta, haloumi, mozzarella and Camembert however, the proportion of saturated fatty acid content varies. There is also a range of average sodium content across different hard and semi-soft cheeses; for example, on average haloumi has one of the highest sodium contents (2900mg/100g) whilst mozzarella has one of the lowest (520mg/100g). However, few cheeses offer both a low sodium and low fat content, cottage cheese and mozzarella perhaps being an exception in the examples given in the table below (average nutrient values from FSANZ 2019, Australian Food Composition Database)[18].

Cheese	**Energy (incl DF) kJ/100g**	**Total fat g/100 g**	**Saturated fat g/100g**	**Moisture g/100g**	**Sodium mg/100g**
Blue	1571	32.4	20.71	41.4	1090
Brie	1502	31.5	20.48	46.3	580
Camembert	1254	23.8	15.56	53.5	570
Cheddar type	**1663**	**32.8**	**21.65**	**34**	**684**
Cottage cheese	529	5.7	3.47	75.4	277
Edam	1510	27.2	17.22	39.9	900
Fetta	1136	22.3	14.16	54.8	1100
Goat cheese, firm	1502	31.3	20.74	44.9	538
Haloumi	1050	17.1	11.03	51.1	2900
Mozzarella	1213	22.1	14.37	47.5	522
Parmesan, fresh	1690	28.8	18.23	28.1	1300
Processed cheese	**1254**	**23.9**	**16.04**	**48.4**	**1420**
Soy cheese	1238	28	3.68	59.9	685

Ref 18 (DF = dietary fibre)

Reducing the sodium content for more brands to <710mg/100g in the cheddar type cheese category and to <1270mg/kg for processed cheeses (where it is technically feasible from a texture, taste and food safety point of view) will provide an extended choice for consumers who are trying to follow the ADGs in relation to dairy products.

The reduction in sodium levels proposed to enable reformulation targets for regular cheddar type cheeses and processed cheeses are not likely on their own to affect the macronutrient profile of the product, so will not impact negatively on the assigned HSR. If the reduction of salt levels is sufficient to lower the assigned number of points for sodium content, then the HSR may change to a higher rating.

Reducing the fat content of cheddar type cheeses and processed cheeses reduces the sodium content and increases moisture content, the resulting change in macronutrient profile per 100 grams may result in a higher star rating (lower energy and fat, higher protein content). Increasing the moisture content of cheese is also an option to reduce sodium content providing food safety is ensured.

3.6 Public health risk - Reduced sugar may have the negative outcome of reduced population consumption of wholegrains

Comments in submissions

- Reduced sugar may have the negative outcome of reduced population consumption of wholegrains (from muesli bars)

Risk Assessment

The ADGs recommend enjoying a variety of nutritious foods from five food groups, including grain foods, recommending consumption of mostly wholegrain and/or high fibre cereal varieties (Guideline 2) but not those grain-based foods with high levels of added sugars, saturated fat or salt (Guideline 3)[15]. The ADGs are based on an extensive body of scientific evidence, for cereals there is evidence for the association of consumption of cereal (mostly wholegrain) foods with reduced risk of cardiovascular disease, type 2 diabetes and weight gain[19].

Although the definition of wholegrain varies, it is defined in Standard 2.1.1 Bread and bread products in the Australia New Zealand Food Standards Code as:

wholegrain means the intact grain or the dehulled, ground, milled, cracked or flaked grain where the constituents—endosperm, germ and bran—are present in such proportions that represent the typical ratio of those fractions occurring in the whole cereal, and includes wholemeal.

wholemeal means the product containing all the milled constituents of the grain in such proportions that it represents the typical ratio of those fractions occurring in the whole cereal.

A wide variety of sweet and savoury foods in our diet contain cereals, including the muesli bar category. The nutrient composition of different brands of muesli bars will determine whether they are likely to be a good food choice according to the ADGs. There is a range of saturated fat content from 1.27-8.85g/100g, however choosing the low saturated fat muesli bar does not necessarily mean it fits within the ADGs, as some are higher in sodium and/or added sugars than others. The HSR of the range of muesli bars may give a better indication of overall fit with the ADGs as the rating takes account of energy, protein, dietary fibre, sugars, saturated fat and sodium content of the food.

The typical nutrient content of different muesli style bars, taken from the Australian Food Composition Database[18] is given below. The dietary fibre may be from wholegrain, fruit and/or nuts in the product so cannot be used to indicate the relative level of wholegrain in the muesli bar products.

	Energy # kJ/100 g	**Protein** g/100 g	**Total fat** g/100 g	**Sat fat** g/100g	**CHO*** g/100g	**Total (Added) sugars** g/100 g	**Dietary fibre** g/100g	**Sodium** mg/100 g
Bar, muesli, plain or with dried fruit	1618	6.8	11.7	3.24	62.8	19.6 (11.5)	6.2	144
As above, chocolate coated	1653	6.1	11.5	6.65	64.1	20.1 (12.6)	6.4	70
As above, yoghurt coated	1675	6.6	14.1	8.85	59.5	23.1 (12.3)	6.4	74
Bar, muesli with nuts	1722	8.6	13.8	3.67	60.3	17.6 (14.4)	6.8	162
Bar, snack, fruit filled, baked	1400	3.9	3.0	1.27	71.1	31.4 (25.6)	4.5	199

Ref 18

Energy including dietary fibre

*Available carbohydrate, including sugar alcohols

Reformulation targets

The proposed sugars targets for muesli bars are based on an assessment of the current range of products in the Australian market. It was assumed likely that the target was technically feasible if there were existing products on the market that were at or below the proposed target.

The proposed targets for muesli (cereal) bars are for a 10% reduction in sugar across defined products containing over 28g sugar/100g, and a reduction in sugar to 25g/100g for products containing between 25-28g sugar/100g. As the table above indicates, some brands of muesli/cereal bars will already meet targets, as the average total sugar content for some muesli types is <25g/100g. If the rest of the range reformulates to meet the sugars targets there will be an improved consumer choice of muesli bars more likely to meet the ADGs as part of a healthy diet, providing the saturated fat and sodium content are not increased as a result of sugar reduction.

Potential impact of reducing the sugar content of muesli bars on wholegrain content

The impact of reducing the sugar content of muesli bars on contribution to wholegrain content is not easy to predict, as manufacturers have flexibility in implementing reformulation targets and if sugar is reduced and/or other ingredients added, this could alter the relative contributions from each ingredient per 100g. Overall, a small change in the contribution of muesli bars to total wholegrain intake due to reduction of sugar content is possible (may be an increase or decrease), but as there are many other sources of wholegrains in the diet, such as breads, breakfast cereals, rice, pasta etc, it is not expected to impact on total wholegrain intakes to any great extent.

The Australian Food Composition Database does not contain information on wholegrain content as this information cannot be determined by analysis, so wholegrain intakes were not assessed in the 2011-13 Australian Health Survey. Results from the 2011-12 National Nutrition and Physical Activity Survey indicate that overall muesli or cereal style bars contributed 0.7% of total sugars and 0.8% of added sugars in the Australian diet, with a range of 0.2-2.2 % added sugars over different age groups, the highest being for 2-8 year olds(20).

In January 2017, the Grain and Legumes Nutrition Council (GLNC) examined the nutritional profile of 54 cereal, 94 muesli/oat bars and three legume based bars (total 151 bars) found in four different retail supermarkets in North Sydney/Neutral Bay area of Sydney. The review used on pack information, including nutritional information, claims, logos and ingredients to determine the amount of fibre, protein, saturated fat, sodium, sugars and whole grains per serve per 100g(21). The GLNC *Code of Practice for Whole Grain Ingredient Content Claims* guides the use of whole grain content claims in Australia and New Zealand(22). The minimum required to make a whole grain ingredient content claim is 8g of wholegrain per serve, a high claim requires ≥16g/serve - <24g/serve, and a very high claim ≥ 24 g/100g. Nearly a third (31%) of muesli/oat based bars assessed were high in wholegrain according to the GLNC Code, where wholegrain content could be assessed from the label (85% muesli/oat based bars); a further 64% could make claim and 4% a very high wholegrain content claim. For cereal bars, 20% of cereal bars were high in wholegrain, where wholegrain content could be assessed (27% cereal bars); a further 80% could make a claim.

According to the 2017 GLNC Consumption and Attitudes Study of over 1000 people, 13% of Australians aged 2-70 years ate muesli bars and 11% ate other bars. Overall, GLNC reported that since 2014, consumption of all grain foods had remained steady at six serves per day, split into an average of four serves of core grain foods a day and two serves of non-core grain foods. Core grain foods are defined as those recommended as part of a healthy diet, like bread, breakfast cereals, rice and pasta. For wholegrain intakes, 30% of Australians were assessed as eating enough wholegrain, i.e. amount recommended by GLNC of 48 grams per day(23).

A range of muesli and cereal style bars are currently available on the market, some of which already meet the reformulation targets for sugar content. The impact of reducing the sugar content of muesli bars on their contribution to total wholegrain content is not easy to predict, as manufacturers have flexibility in implementing reformulation targets.

As there are many other sources of wholegrains in the diet, such as breads, breakfast cereals, rice and pasta, a reduction in the sugar content of muesli bars it is not expected to change total wholegrain intakes to any great extent.

3.7 Public health risk – Reducing sodium in bread may reduce iodine intake

Comments in submissions

- Bread in the Australian food supply is mandatorily fortified with iodine, making salt in bread an important vehicle for a shortfall mineral. It is important to monitor the impact of sodium reformulation, specifically reducing the sodium content of bread, on the potential for reducing the iodine intake of at risk populations.

Risk Assessment

Iodine is a naturally occurring mineral and an essential nutrient for life. Adequate intakes of dietary iodine by Australians, particularly females of child-bearing age and breast-feeding mothers is important for health and to reduce possible iodine-deficiency health problems such as impaired neurological function in babies and young children. Mandatory iodine fortification was implemented in Australia and New Zealand in 2009 as a public health measure, intended to address the re-emergence of iodine-deficiency in some areas of both countries. A more recent review by Zimmerman of several countries with reported iodine inadequacy in their populations indicates that '*in moderate-to-severely iodine-deficient areas, controlled studies have demonstrated that iodine supplementation before or during early pregnancy eliminates new cases of cretinism, increases birthweight, reduces rates of perinatal and infant mortality and generally increases developmental scores in young children by 10–20%....In nearly all regions affected by iodine deficiency, salt iodisation is the most cost-effective way of delivering iodine and improving maternal and infant health*'[(24)].

The Australia New Zealand Food Standards Code includes mandatory requirements to use iodised salt in bread making in both Australia and New Zealand, except for organic bread and bread mixes for making bread at home (Chapter 2, Standard 2.1.1 Cereal and cereal products).

Voluntary fortification permissions in the Australia New Zealand Food Standards Code allow manufacturers to add iodised salt to bread mixes and other foods, which can provide alternative dietary iodine sources for people who do not eat bread sold at retail level. Labelling requirements must be adhered when iodised salt has been used in a food product on a voluntary basis, it must be listed in the ingredient list of food labels. Unpackaged bread and bread that is made and/or packaged at the point of sale is not required to be labelled. However, this information may be available on request.

<u>Potential impact of a salt reduction program for bread on iodine intakes</u>

The level of iodine permitted to be added to iodised salt for use in bread making and on a voluntary basis is 25-65mg iodine/kg salt (Chapter 2, Standard 2.10.2 Salt and salt products). The intention of the mandatory fortification standard was that the permitted level of iodine in salt could be altered over time, should monitoring indicate a change in population iodine status that required an increase or decrease in iodine levels in iodised salt to achieve the desired public health outcome[25]. A reduction in the salt content of bread as an outcome of the PRP could impact on population iodine intakes and may require an adjustment in the iodine content of iodised salt, depending on whether the voluntary use of iodised salt in processed foods, proportion of imported foods available (may or may not contain iodised salt) and/or addition of salt at the table by consumers also changes.

Experience with iodine fortification in other countries was reviewed by FSANZ in 2007 as part of its P1003 proposal, International experience with iodine fortification[25]. In Switzerland for example, iodine levels in salt were increased by 25% in 1999 (from 15 mg/kg salt to 20 mg/kg) as part of a national iodised salt program as monitoring data for the target population indicated their iodine status had not been improving as expected with the use of iodised salt in the food supply. The change resulted in an improvement of the iodine status for the target populations, children and pregnant women, from marginal to clearly sufficient[24,26].

Monitoring in Australia and New Zealand

The then Australia and New Zealand Food Regulation Ministerial Council (the Ministerial Council, now referred to as the Forum) requested in 2009 that a comprehensive and independent review be initiated 2 years after their implementation of the mandatory fortification standard, and that the Food Regulation Standing Committee and the Australian Health Ministers' Advisory Council oversee the review process. The three-stage review comprised an assessment of:

- food industry compliance and impacts on enforcement agencies
- population health effects of mandatory folic acid and iodine fortification
- the effectiveness of the mandatory folic acid and iodine fortification initiatives.

For iodine fortification, several components were monitored for both the target and non-target populations in Australia and New Zealand:

- iodine content of bread
- trends in population consumption patterns of bread
- iodine intakes
- iodine status.

The Australian Institute of Health and Welfare (AIHW) was commissioned by the Department of Health (Health) to prepare a report that monitored progress in Australia and New Zealand after two years of mandatory fortification. The AIHW first published a Baseline report for monitoring in May 2011 detailing the data collections to be used for iodine and folic acid monitoring purposes[27], and, second a progress report in June 2016 of the Health impacts of mandatory iodine and folic acid fortification two years post-implementation[28].

A summary of the 2016 AIHW report indicated that *Post-mandatory iodine fortification in Australia, the population was consuming sufficient iodine to address the recent re-emergence of mild iodine deficiency at a population level. Post-mandatory iodine fortification in New Zealand, there was in July 2017 a modest improvement in iodine intakes; however, some groups were still at risk of mild iodine deficiency'*[28].

For Australia, the 2011-13 Australian Health Survey (AHS) collected information on food consumption and when combined with the revised nutrient composition database[12] provided an updated estimate of usual sodium and iodine intakes for target and non-target groups, in the general population[6]. Information on population iodine status was provided in the biomedical survey component (medium urinary iodine concentrations, MUIC). Iodine status was adequate at a general population level. Overall, usual iodine intakes had increased in 2011-12 consistent with the biomedical results, with the percentage contribution from bread and bread products to total iodine intakes also increasing. However, females aged 19 years and over were four more times as likely as males to have inadequate intakes (prevalence of inadequate intake of iodine was 2% adult males, 10% adult females)[6,29].

For New Zealand, various studies were undertaken by the Ministry for Primary Industries as part of the New Zealand Nutrition strategy and research program: the sodium and iodine content of bread, (ESR 2009)[30], levels of iodine in retail salt (ESR 2009)[31], dietary iodine intake of New Zealand children following fortification of bread with iodine (MAF 2012)[32] and a supplement to the 2016 AIHW report on mandatory iodine fortification in New Zealand (MPI 2016)[33]. In New Zealand the improvement in iodine status of target groups was less than expected though the original studies included in the AIHW 2016 review were from sub-national studies. Provisional results from a larger national survey, the 2014/2015 New Zealand Health Survey (NHS) indicate target populations are within the range for adequate iodine status[34].

The information on iodine intakes pre- and -post implementation of mandatory fortification in the 2016 AIHW report was provided by FSANZ[35]. The 2011-13 Australian Health Survey (AHS) food consumption data were unfortunately not available for use by FSANZ for these estimates of so previous national nutrition survey data were used.

However, the iodine content of bread used in the FSANZ modelling exercise was up to date, based on analysed iodine content of bread products from surveys undertaken pre-implementation and post-implementation from 2010-2013. The bread survey results indicated bread had been fortified with iodine to the level expected, that is, in accordance with the mandatory fortification standard. The sodium content of bread was also analysed in the 2010-2013 bread surveys and although not published separately the results were incorporated into the AHS food composition database (AUSNUT 2011-13)[12]. Sodium levels of many breads had decreased since the previous children's survey database (AUSNUT 2007) was published, reflecting the outcomes of the previous voluntary food reformulation program, the Food and Health Dialogue, one component of which was to reduce sodium levels in bread. Despite the reduction in salt levels in bread, usual iodine intakes reported from the AHS had increased post-implementation of fortification, as noted above.

A final evaluation report on the mandatory fortification initiative was published by the Coalition of Australian Governments (COAG) Health Council in June 2017, Effectiveness and cost-effectiveness of mandatory folic acid and iodine fortification[36]. In addition to the public health impacts described in the second report, it was found that the fortification program had successfully reached the public health objectives in Australia and New Zealand of addressing the re-emergence of mild iodine deficiency. In both countries the effectiveness of mandatory fortification was found to be superior to pre-mandatory fortification programs. However, the higher iodine requirements of pregnant and lactating women were not met and supplementation of these subgroups on an ongoing basis is required.

The level of iodine in iodised salt permitted in the Australia New Zealand Food Standards Code was not changed as a result of the 2017 COAG evaluation.

Future monitoring

To assess if iodine intakes and iodine status are remaining within the acceptable range and hence whether the level of iodisation of salt and/or the selection of food vehicles continue to be suitable to meet the stated public health objectives of a mandatory fortification program, the monitoring program should be continued and data evaluated at regular intervals. The main source of representative monitoring data for both countries is likely to be national health surveys, providing they include nutrition and biomedical survey components and an updated food composition database on a periodic basis. Bread surveys of a wide range of products may be required from time to time to supplement the iodine and sodium content data for bread in the national food composition database.

For Australia, the next AHS to include a nutrition and biomedical component is proposed for 2021-23 but is currently unfunded. For New Zealand, information on iodine intakes and iodine status were updated following the completion of the 2014/2015 New Zealand NHS.

The intention in establishing a mandatory iodine fortification standard was that the permitted level of iodine in salt could be altered over time, should monitoring indicate a change in population iodine status that required an increase or decrease in iodine levels in iodised salt to achieve the desired public health outcomes.

Updated national nutrition surveys will be an important part of monitoring the impact of the PRP and re-evaluating the reformulation targets and scope as required. Specifically, monitoring the impact of the PRP on the use of salt and iodised salt in the food supply and an assessment of the outcomes on sodium and iodine intakes, and sodium and iodine status, for the relevant target and non-target populations on a regular basis would supply the required information.

3.8 Public health risk – Concern that advice to consume a low fat diet is outdated

Comments in submissions

- The low fat advice over the last 50 years is what caused the obesity crisis, continuing on will only worsen it

Risk Assessment

The Select Committee into the obesity epidemic in Australia Senate Report of 2018 recognizes that in Australia, rates of overweight and obesity have risen dramatically in recent decades in all age groups[37,38]. The link between overweight and obesity and poor health outcomes is well established. Although at present, Australia does not have an overarching strategy to tackle obesity, there is evidence around the need for a wide ranging array of multi-strategies to address obesity. The Senate Report also recognises that while it is true that the causes of the rise in overweight and obesity can be attributed to multiple systemic factors, there is no doubt that a major contributor is poor diet and in particular the increased consumption of processed and discretionary foods[37].

There are several strategies that are likely to improve provision of healthier food and healthier food choices, including improved education, food reformulation and better food labelling, such as a front-of-pack labelling system like the HSR system. The PRP is one of these strategies implemented as part of a wider health program and has identified three nutrients (sodium, sugars and saturated fat) as targets for reduction in a variety of food types, based on available scientific evidence.

The ADGs recommend limiting the intake of food high in saturated fat, added salt, added sugars and alcohol (Guideline 3), and whilst recommending consumption of dairy foods and/or dairy alternatives suggests these should be mostly reduced fat (Guideline 2)[15]. The ADGs are based on an extensive body of scientific evidence and recommend caution in choosing food high in fat because of the implications for weight gain and cardiovascular heart risk[19]. Results from the 2011-13 Australian Health Survey indicate that approximately one in eight males (13%), one in six females (16%) and approximately one in five children aged 14-18 years (22 % females, 19% males) had fat intakes above the Acceptable Macronutrient Distribution Range[29]. This nutrient reference value was established by the National Health and Medical Research Council in 2006 such that fat intakes should contribute from 20-35 % total energy from the diet, the remaining energy should be from carbohydrates (45-65%) and protein (15-25%)[39].

Total energy from the diet is the variable that affects weight[19]. Fats have the highest energy value per gram of all the macronutrients (fat 37 kJ/g, alcohol 29 kJ/g, sugars, 16 kJ/g, carbohydrates including dietary fibre 17 kJ/g, protein 17 kJ/g[18]. Selecting foods that are lower in fat content may assist in reducing overall energy intake. The PRP aims to provide a wider range of low saturated fat foods for consumers to choose from.

Replacing fats with other macronutrients, such as carbohydrates or polyols, in individual foods will reduce total energy content, however the extent to which this is technically feasible whilst retaining the nature of the food will depend on the food matrix. Manufacturers retain flexibility as to how they implement the reformulation targets.

Replacing saturated or trans-fat with mono- or poly-unsaturated fats on a per gram basis does not reduce the total energy content of the foods, however there is evidence that there may be health benefits. The FAO Expert consultation on fats and fatty acids on human nutrition (reported evidence that replacing saturated fatty acids with polyunsaturated fatty acids decreased the risk of coronary heart disease[40]. There is also evidence that replacing saturated fats with monounsaturated fats also has some health benefit[19].

3.9 Public health risk – Concern that the reduction targets are not stringent enough

Comments in submissions

- Risk to public health that targets are too conservative / targets should be reduced further.
- A voluntary reformulation program may not be adopted at sufficient levels to have public health benefit.
- Monitoring and evaluation may be insufficient.

Risk Assessment

The RWG acknowledges that reformulation is just one strategy to improve population health outcomes. However, the targets need to be feasible for industry to implement.

Monitoring and reporting will allow the Healthy Food Partnership to assess the effectiveness of the PRP after the initial 4 year implementation period.

The RWG consulted with industry to ensure the feasibility of the targets and to encourage their involvement in the PRP. Where possible, the targets have been aligned with the HSR system, which is also a voluntary program with good and increasing uptake.

3.10 Public health risk - Unhealthy aspects of the replacement ingredient and increased artificiality.

Comments in submissions

- Replacement ingredients may be less healthy than those that were originally used. For example, if saturated fat is replaced by industrially produced trans fatty acids or sugar.

Risk Assessment

The PRP provides flexibility for food industry to self-determine how the reformulation target may best be achieved, within the broader intent of the Healthy Food Partnership which is to increase the overall healthfulness of the food supply.

The RWG is also mindful of industry feedback that consumers are less accepting of artificial additives and long lists of unidentifiable ingredients; as well as sensory and consumer acceptability testing. The RWG is confident that industry will continue to keep all of these aspects in mind when making business decisions about how to reformulate products.

3.11 Public health risk – Unknown impact of increased consumption of replacement ingredients, e.g. intense sweeteners

Comments in submissions

- Where nutrients such as sugar and sodium are reformulated with sugar and sodium substitutes, we question the impact of this, and the subsequent change to population consumption patterns. For example, if an entire food category has sugar replaced with intense sweeteners, because targets are set for sugar reduction - this many increase consumption of intense sweeteners and lead to unintended consequences, not anticipated by regulators when conducting dietary modelling to set safety limits for these types of ingredients. We don't eat single nutrients - it is important to consider the food as a whole - reducing public health sensitive nutrients does not necessarily mean that the resulting product is healthier or more nutritious overall.
- Please do not steer manufacturers to add artificial sugar substitutes that are now implicated in many problems such as cancer, diabetes and memory loss in the elderly; weight gain in younger people.
- Replacing sugar with sugar alcohols or other sweeteners, of which consumer acceptance may be low, and health implications long-term uncertain.

Risk Assessment

Intense sweeteners must be assessed for safety by FSANZ and are approved only if it can be shown no harmful effects are likely to result from their use.

Comprehensive pre-market assessments and surveys of intense sweeteners by FSANZ have found that there are no safety concerns for consumers with respect to intense sweeteners and dietary exposure is less than the established acceptable daily intakes for each intense sweetener.

For example, aspartame, one of the most commonly used artificial sweeteners has been the subject of comprehensive reviews by FSANZ, the Food and Agricultural Organization/World Health Organization Joint Expert Committee on Food Additives (JECFA), the European Food Safety Authority (EFSA) and the US Food and Drug Administration (USFDA). In December 2013 EFSA completed a full risk assessment on aspartame and concluded it is safe at current levels of exposure[41]. The risk assessment involved a review of all scientific research on aspartame and its breakdown products.

In addition, FSANZ is currently undertaking a joint project with the Ministry for Primary Industries in New Zealand to further review intense sweeteners.

3.12 Public health risk - Substituting sodium chloride with potassium chloride

Risk Assessment (NOTE: The following is the executive summary of a risk assessment undertaken by Dr Paul Brent. The full document can be provided upon request.)

Reformulation of food to lower sodium and increase potassium would seem to have public health advantages, provided the benefits outweigh the risks.

A recent review suggests that the potassium chloride-based salt substitutes are the most important class of salt substitutes[42]. Potassium chloride is a naturally occurring mineral salt, which is obtained from rock and sea salts in a manner similar to the extraction of sodium chloride. The use of potassium chloride as a technique to reduce sodium in food products is expected to increase in the coming years. Potassium chloride is generally similar to sodium chloride, but is characterised by slightly less intensive salty taste with a certain degree of bitterness and acrid and metallic tastes. To avoid these unwanted sensory properties, numerous taste-improving agents and formulation concepts have been used. According to the review quoted above, “the most important classes of taste-improving agents that have been employed in numerous formulation concepts of potassium chloride-based salt substitutes are nutritionally acceptable mineral salts; food acids, amino acids, and their nutritionally acceptable salts; simple carbohydrates and sugar substitutes; food polymers; umami ingredients; spices, vegetables, and flavours; miscellaneous taste improvers; as well as a plethora of their specific combinations.

Depending on the format of the food, different levels of potassium chloride have been used to replace sodium chloride without compromising on sensorial aspects. For example, in watery solutions the off-taste of potassium chloride can initially be perceived at a concentration of 20%[43]. In pizza crust, replacement of 25% has been documented as possible[44], in brown and white bread 30%[45, 46] in cheddar cheese 46%[47] and in feta cheese even up to 50%[48].

It is important to understand the potential impact that increased industry-wide use of potassium chloride could have on the diet of the general population. This risk assessment shows that reformulation of food by adding potassium chloride to replace sodium chloride at a level of up to 21% should not result in any adverse health effects in healthy adults, children or infants. There are several very robust arguments available from the recent peer-reviewed literature to support this conclusion. Potassium chloride cannot be used in unlimited quantities as at higher levels it loses its ability to convey saltiness and can have an off-taste, often described as bitter, chemical and metallic. Depending on the format of the food, different levels of potassium chloride have been used to replace sodium chloride without compromising on sensorial aspects.

The safety of oral consumption of potassium chloride is supported by the natural occurrence of potassium in foods. As a result, potassium chloride has gained regulatory acceptance for use in food products in the United States and European Union and numerous other international scientific bodies and regulatory authorities[49-52].

Expert bodies agree that increasing potassium consumption from food in the population poses little risk for adverse effects[52-54]. While there is currently no established upper limit for potassium intakes, based on estimates of current intakes in European countries, the European Food Safety Authority (EFSA) states that the risk of adverse effects from potassium intake from food sources at 5000–6000 mg/day is considered low for the generally healthy population. Moreover, long-term intake of potassium supplements at levels of 3000 mg/day on top of usual intake from foods is also considered low risk for the general healthy adult population[55]. A recent study estimated the potassium intake for in the United States, Mexico, France and United Kingdom is 80%, 95%, 77% and 95%, respectively, below the WHO guideline for potassium[56].

Implications of Sodium Replacement for Dietary Intakes of Potassium

The potassium intakes for the Australian population across a range of age groups: 2-3 yrs, 4-8 yrs, 9-13 yrs, 14-18 yrs, 19-30 yrs, 31-50 yrs, 51-70 yrs are shown in Table 1. The Nutrient Reference Values (NRVs) are expressed as Adequate Intakes (AIs). The AI was set at the highest median intake for the various age categories of male and female intakes from the 1995 NNS and 2003 NZ NNS. There is no UL for potassium. In Table 1, Australian adult potassium median usual intakes are compared with Australian AIs for potassium, which are slightly different from the UK and WHO NRVs (Australia adult males 3800 mg/day, females 2800 mg/day; UK/WHO adults 3500 mg/day). The EU Recommended Daily Amount (RDA) for potassium in adults is 3.1-3.5 g per day (79.5 – 89.7 mmol per day).

Data from the usual mean, median and AIs for Australia (Table 1) show that mean and median potassium intakes in Australia were similar to, or in the same range as those reported in the UK[(58)], and median intakes were generally less than the relevant AIs.

Exposure Assessment for Age Groups 19-64+ and 19+ Years Adults

The calculations that follow focus on exposures in adults (aged 19-64 and 19+ years) as the large majority of people who would be most vulnerable to an increase in potassium intakes fall in this age range.

Information about the exact extent to which potassium might be used to replace sodium in food products in Australia is not available. However, as a reasonable model for comparison it is proposed to use the proportional increase in potassium intakes from the UK modelling results from their maximum replacement scenario[59] (UK assumed 25% replacement for eligible foods except breads, where they assumed 15% replacement). This resulted in an estimated 21% increase in potassium intakes for adults, both for 19-64+ and 19+ (men had a slightly higher increase then women but it is assumed the generic figure is suitable to apply to the Australian published median usual potassium intakes for this purpose). The UK baseline potassium intakes are in the same range as the Australian intakes and the proportion of processed foods in the food supply is similar so it would seem to be a reasonable model.

As can be seen in the table below, when the 21% increase to the Australian adult potassium median usual intakes is applied and compared with Australian AIs for potassium, there would be some adults with estimated intakes slightly over the relevant AI. However it should be noted that this is a maximum replacement scenario, the AIs are derived from median potassium intakes from the Australian 1995 survey and the 2003 NZ NNS and there is no UL. Moreover, these calculations and the use of the AI are likely to over-estimate the maximal increases in potassium intakes, as they base the potassium replacement on the total sodium content of relevant foods, including naturally occurring sodium, rather than the added sodium content (i.e. that which could be replaced). However, from the UK data the limited recipe data that are available from food manufacturers suggest that the assumption of 15/25% replacement for eligible foods is reasonable.

		Age Group (years)							
	Unit	2-3	4-8	9-13	14-18	19-30	31-50	51-70	71 and over
				Usual intakes - Potassium					
Potassium				Males					
Mean intake	mg/day	2170	2259	2729	2909	3187	3289	3172	2969
Median (50th)	mg/day	2150	2239	2706	2888	3170	3271	3151	2946
Median +21%						3835.70	3957.91	3812.71	3564.66
AI	mg/day	2000	2300	2500	2600	2800	2800	2800	2800
Baseline as %AI		107.5	97.3	90.2	80.2	83.4	86.1	82.9	77.5
Scenario at %AI						100.9	104.2	100.3	93.8
				Females					
Mean intake	mg/day	1925	2006	2469	2396	2449	2618	2717	2542
Median (50th)	mg/day	1900	1983	2425	2343	2405	2575	2671	2499
Median +21%						2910.05	3115.75	3231.91	3023.79
AI	mg/day	2000	2300	2500	2600	2800	2800	2800	2800
Baseline as %AI		95	86.2	97	90.1	85.9	92	95.4	89.3
Scenario at %AI						103.9	111.3	115.4	108

Ref 30: Baseline mean and median potassium intakes taken from ABS Usual nutrient intakes, Table 6.1

The scenario modelling used here shows that in males, baseline median (50th) potassium intake levels across the age ranges 4-8, 9-13, 14-18, 19-30, 31-50, 51-70 and 71 and over were lower than the AI. Only for 2-3 year old males was the baseline potassium intake level over the AI (107.5%). In females, all baseline potassium intake levels were below the AI.

For adults scenario modelling indicates there would be only a very small percentage increase in potassium intake over the AI at the replacement level of 21% (maximum for adult males of 104.2% of the AI for 31-50 year old. Under the scenario modelling the maximum increase in potassium intake for adult females as a percentage of the AI was 15.4% for the age group 51-70 years (scenario as a % of the AI 103.9% for 19-30 years; 111.3% for 31-50 years; 115.4% for 51-70 years and 108% for 71 and over). Therefore, using the scenario modelling, which is considered a conservative overestimate, the percentage increases in potassium usual median intakes across the age ranges in both adult males and females compared to the AI are relatively small.
To put the scenario modelling used here into perspective in relation to possible effects on human health, salient excerpts from the UK COT study(57) are relevant here:

> "In people with normal renal function, hyperkalaemia from excessive intake of potassium is very uncommon. Possible causes include overdose of potassium supplements, massive blood transfusion with hypoperfusion, and accidental ingestion of potassium chloride crystals used in water softeners. Short-term intakes of up to 15 g/day potassium have been reported not to result in plasma potassium concentrations outside the normal range, provided that intake is spread over the day and fluid intake is sufficient."
>
> "The large majority of cases of hyperkalaemia (>80%) occur when potassium excretion is impaired by a medical condition or by the use of certain medications in a patient with some degree of underlying renal dysfunction. Dietary salt substitutes, potassium supplements, potassium penicillin therapy and drinking potassium softened water may all induce hyperkalaemia in pre-disposed individuals(57).
>
> Similar factors affect the rate at which hyperkalaemia can develop. A randomised sample of 551 hospitalised patients was analysed in a study by Indermitte et al.(59). Compared to

the drug treatment at entry, significantly more patients were treated with drugs associated with hyperkalaemia such as heparins, ACE inhibitors or angiotensin receptor blockers (ARBs), potassium, supplements, potassium sparing diuretics and/or NSAIDs selective cyclo-oxygenase 2 inhibitors during hospitalisation. Risk factors associated with the rapid development of hyperkalaemia were the use of potassium supplements, severe renal impairment, use of ACE inhibitors or ARBs, use of potassium sparing diuretics and diabetes mellitus. The rate at which hyperkalaemia developed was significantly increased in patients with two or more risk factors. Dose effects were reported for the use of potassium, supplements and potassium sparing diuretics only. In patients treated with high dose potassium supplements (> 3 g/day) the median rate of change in the daily increase in serum potassium was higher than in those treated with low dose supplements (0.48 vs 0.40 mmol/L) p = 0.006.

Healthy adults would not be expected to suffer harm from increased dietary potassium. As stated previously, the body is able to cope with both short- and long term increases in potassium intakes without substantial alterations to plasma potassium concentration. Through synchronised changes in renal and extra-renal handling, excess potassium will be excreted in due course to maintain a zero potassium balance[55,60]. The UK COT noted that there is no reason to expect that healthy pregnant women would be unusually vulnerable to higher potassium intakes. Women require a positive potassium balance during pregnancy[61].

From the information available in the literature, and particularly from the information quoted from the UK COT study[57], the above results for the present review clearly indicate that any adverse health issues due to the increased potassium intake in either healthy males or females would be highly unlikely. Given the reserves in the body’s capacity to maintain potassium balance, healthy adults and children older than one year would not be expected to suffer any harm from increases in dietary potassium of the magnitude that might result from sodium-replacement. Adverse effects would not be expected in healthy infants since significant exposure to potassium-based replacements is unlikely to occur until they start to consume family food, by which time the function of the kidney will have undergone substantial maturation. Moreover, hyperkalaemia does not appear to be a problem currently in healthy infants from dietary exposures alone in the UK and Europe, and this is also likely to be the case in Australia[57].

Potassium-based replacement could, however, affect the health of people with major impairment of renal function because of Chronic Kidney Disease (CKD) or other morbidity, and those taking medications such as Angiotensin Converting Enzyme (ACE) inhibitors and potassium-sparing diuretics that reduce renal excretion of potassium. Most, but by no means all of these vulnerable individuals will be elderly. In theory, patients with diagnosed CKD and those taking medicines that predispose to hyperkalaemia could be advised by their doctors to avoid foods in which sodium has been replaced by potassium. However, this will only be practical if the food products concerned are clearly labelled, and suitable alternatives are readily available that do not contain potassium-based replacements.

It should be emphasised that there are uncertainties in the assumptions made and calculations that have been presented. For example the use of the AI for potassium as the NRV, which is based on median intakes from the 1995 survey and 2003 NZ NNS, and that it is unclear to what extent potassium-based replacement would be implemented in practice – both the range and number of food products in which it would be used, and the level of substitution within those foods. There is also no information available about the distribution of tolerance to potassium among people with unrecognised vulnerability to high dietary intakes, or that adverse effects of increased potassium intake would increase in proportion to the prevalence of daily intakes of potassium greater than the AI.

The uncertainties could be reduced by surveys of the incidence and characteristics of life-threatening hyperkalaemia, and better information about the extent to which replacement would occur in different foods. In addition, if partial potassium-based replacement for sodium chloride were to be implemented, it might be advisable to monitor its application, along with temporal trends in the incidence of hyperkalaemia, both in patients with known vulnerability, and in those not previously recognised as being at risk. Ideally, such monitoring should include collection of baseline data before the salt-replacement began. At the time of this review, The Department of Health is exploring the collection and monitoring of this data, including baseline levels from when the PRP was known to industry (October 2018).

Potassium-based replacement for sodium chloride and sodium-based additives would not be expected to cause any adverse effects in healthy adults, children or infants. Potassium-based replacement could, however, threaten the health of people with major impairment of renal function because of CKD, and those taking medications such as ACE inhibitors and potassium-sparing diuretics that reduce renal excretion of potassium. Most, but by no means all of these vulnerable individuals will be elderly. These vulnerable populations will need to continue to be managed by their medical doctors and clinical dietitian, and could be advised to avoid foods in which sodium has been replaced by potassium. Food products that are clearly labelled and readily available suitable alternatives that do not contain potassium-based replacements would make sodium replacement practical. The launch of the PRP will be accompanied by communications to medical practitioners and dietitians about the changes. The Department of Health will consider the inclusion of Potassium on the Nutrition Information Panel.

If partial potassium-based replacement of sodium chloride and sodium-based additives were to be implemented, it would be advisable to monitor its application. In deciding whether to encourage potassium-based replacement of sodium chloride and sodium-based additives, policy-makers will need to balance the expected benefits against these potential adverse effects. If replacement were at a lower level than has been assumed in the above calculations, then adverse effects would be less frequent. If required, other scenarios involving lower levels of salt-replacement could be modelled.

3.13 Public health risk - Replacement of sugars across a range of foods in the food supply with sugar substitutes

Risk Assessment (NOTE: The following is the executive summary of a risk assessment undertaken by Dr Paul Brent. The full document can be provided upon request.)

Sugars (sucrose, sucralose, fructose, mannose, lactose etc) are essential macronutrients required to sustain normal human health. However, excess intake of dietary sugar is associated with well-documented adverse public health outcomes. High dietary sugars intake increases the risk of bodyweight gains, obesity, metabolic syndrome and diabetes, which can increase the risk of developing cardiovascular and renal diseases, including stroke, coronary heart disease, heart failure, and kidney failure. Therefore the governments of most countries around the world, including the Australian Government Department of Health, as well as international scientific bodies such as the World Health Organisation (WHO), US Institute of Medicine (IOM), US National Institutes of Health (NIH), National Health & Medical Research Council (NH&MRC Australia), and food regulators such as the European Food Safety Authority (EFSA), US Food and Drug Administration (USFDA) and UK Food Safety Agency (UKFSA) have recommended that programs be put into place to reduce dietary sugars intake. It has been strongly suggested, supported by internationally accepted peer-reviewed research that reduction of dietary sugar will lead to a concomitant reduction in diabetes and related disorders, metabolic syndrome, high blood pressure accompanied by a reduction in cases of cardiovascular and related diseases.

This review has drawn information from a wide variety of sources, including but not limited to the international peer-reviewed literature, information provided from the Department of Health, the Australian Bureau of Statistics (ABS), the Australian Department of Health National Health and Medical Research Council (NH&MRC), and international bodies such as WHO, IOM, UKFSA, NIH, UK Committee on Toxicity (COT), and food regulatory bodies such as the EFSA, New Zealand Ministry of Primary Industries (NZMPI), and Food Standards Australia New Zealand (FSANZ). Internationally accepted risk and exposure assessment methodology was used to compile and analyse the data.

A potential option available to reduce dietary exposure to added and/or total sugar is to simply reduce sugars content across a range of foods, replacing the sweet taste by habituation (so-called "health by stealth"). This option has no real issues in relation to toxicity and human health and safety, and is in fact a potential avenue for a healthier diet given the over consumption of added sugar as alluded to above. However, such an approach may not be technically feasible for the food industry for a number of legitimate and important food technology reasons, and also may not be favoured by consumers. A feasible and practical option is to reformulate foods that are high in added sugars with sugar replacers that are safe and technically feasible, and that convey the favourable traits sought by consumers. For example, replacement of sugars with artificial and intense, and natural sweeteners has been shown to be a practical, safe and technically feasible method already in use across the world. However, the replacement of added sugar by the newly available sweeteners is difficult if the sweetness values or physical and chemical properties of the substitutes differ greatly from those of sucrose, and bearing in mind the toxicological properties of each sugar replacer.

The results of this review illustrates using scenario modelling, within the bounds of the available data and according to the Overarching Principles set by the Healthy Food Partnership (the Partnership), that replacing dietary sugars with sugar substitutes such as natural, artificial and intense sweeteners, which are considered internationally to be safe and suitable sugar replacers, across a range of foods containing added sugars, is very unlikely to result in significant risks or toxicological adverse health effects in the normal healthy population for adults, children and infants.

There are some potential issues to consider in the future. It should be noted that there are possible unresolved health issues related to the use of sugar substitutes, such as the artificial sweeteners, in relation to their effectiveness with regard to producing satiety for the sweet taste imparted by normal added dietary sugars. This has led some researchers to theorise that artificial sweeteners as sugar replacers can in fact have adverse effects on satiety signalling pathways in the brain and the gut microbiome, leading to a counterintuitive claim that consuming high-intensity sweeteners may promote excess energy intake, increased body weight, and other related co-morbidities. Put simply, this theory suggests that because consumers are not getting the energy they would normally get from sugar in food where it has been replaced with artificial sweeteners, they are not sated and consume more food leading to the reverse effect of losing body weight. However, there are other data that do suggest that replacement of sugar with artificial sweeteners does result in weight loss. The jury is still out on this scientific debate and more research is definitely needed to resolve any contentious issues. In addition, intakes of some artificial sweeteners such as aspartame that produce phenylalanine are associated with a specific adverse outcome. Caution should continue to be exercised by patients under the care of medical practitioners and clinical nutritionists in relation to dietary changes that include artificial sweeteners intake for those of the population who are vulnerable, such as those with phenylketonuria.

If reformulation results in the replacement of sugar with sugar substitutes such as natural, artificial and intense sweeteners, then future monitoring the food supply for artificial sweeteners would be an important consideration by government and regulatory bodies.

FSANZ and the NZMPI are currently carrying out a review of artificial sweeteners across both food supplies, and the results may shed some light on overall exposure to each of the available approved sweeteners. It will also be important to monitor the scientific debate which is ongoing regarding the possible public health effects of consuming artificial sweeteners with regard to satiety signalling pathways.

In addition, it should be noted that sugar is a macronutrient where there is likely to be a large amount present in some foods, and consequently a relatively large amount that would need to be replaced in any meaningful reformulation scenario (e.g. 10g of sugar (e.g. sucrose and noting that sucrose is not the only form of sugar to be replaced in a food that contains 100g sugar under a 10% reduction scenario). Although the main reason for the use of sugar in foods is its sweet taste, sugar has many other functions in food technology. The most important among these are that added sugar in foods also acts as a preservative, texture modifier, fermentation substrate, flavouring and colouring agent and bulking agent. The various methods of use of sugar are based on its physical and chemical properties. As such reformulation of foods to reduce added sugar content is much more complex than the situation for a micronutrient such as sodium or potassium where there are only micrograms to replace. In this regard, it is likely that the food industry would need to replace the bulk of the sugar with other constituents such as starches, fibre or dextrins etc (e.g. maltodextrin), resulting in potentially a similar amount of energy as the original food, thereby negating the possible beneficial effect of reducing sugar. The situation with respect to the artificially sweetened beverages is a different scenario, where it should be the case that replacing the sugar content of these beverages with artificial sweeteners may result in less calories.

Current findings suggest that caution about the overall sweetening of the diet is warranted, regardless of whether the sweetener provides energy directly or not. The following points might be useful to consider in any future deliberations:

- Cumulative effect of consuming a range of sweeteners across a period
- Risks to / impact on gut microbiome (emerging field of study)
- Risks associated with impact on satiety (emerging field of study)
- Risks associated with substitution of sugar with (among other things) starches such as maltodextrin or fats (saturated or unsaturated)
- Phenylketonuria (PKU) – risk of limiting the food supply for the subpopulation affected by PKU
- Based on all of the above, is sugar reduction safe as a population level public health measure

3.14 Hypothetical risks for consumers with specific health conditions only

Comments in submissions

- Malnutrition and/or unintentional weight loss in vulnerable populations
  The consideration of malnutrition or unintentional weight loss in elderly and at-risk populations (such as individuals with eating disorders or hypermetabolic states, athletes with high caloric requirements). Such individuals may depend on reformulated products to supply extra calories and flavour to maintain or increase weight and appetite, this may be impacted through reformulation and the reduction of sugar, sodium or fat.
- Chronic Kidney Disease and sodium replacements
  Individuals with Chronic Kidney Disease (CKD) have specific dietary requirements around restricted potassium intake. A common strategy for sodium reduction is to replace sodium chloride with potassium chloride (508) (among others). While this reduces the sodium content of a product, it can have unintended consequences for individuals with CKD. Potassium content of products is to be listed on the Nutrition Information Panel. This would allow consumers to monitor their potassium intake. If the potassium content of products, such as processed meats, increases due to the use of potassium chloride, it would be important for clear messaging and education to consumers and health professionals, individuals with CKD were aware of the changes and could adjust dietary intake accordingly. In the UK, it was concluded that the potential benefits of reducing sodium in foods by using potassium-based sodium replacers outweigh the risks to the small population of individuals with CKD. Non-potassium mineral salts that can also be considered are: ● ammonium chloride (510) ● calcium chloride (509) ● magnesium sulphate (518)
- Diabetes mellitus and sugar reduction
  Individuals who are on tightly controlled insulin regimes and/or those who regulate their carbohydrate intake to manage their diabetes may have to adjust their portions to account for a reduction in sugars of some products. Changes to sugar/carbohydrate content of foods should coincide with clear messaging and education to consumers and health professionals, individuals with Diabetes were aware of the changes and could adjust dietary intake and/or insulin accordingly.
- Cystic fibrosis and sodium reduction
  Individuals with cystic fibrosis are a vulnerable population, as they have higher sodium, fat and, calorie requirements. Changes to sodium, sugar and fat content of foods should coincide with clear messaging and education to consumers and health professionals, individuals with Cystic Fibrosis were aware of the changes and could adjust dietary intake accordingly.

Risk Assessment

While the RWG acknowledges that individuals have differing dietary needs, the PRP is population level health initiative.

Individuals with specific health conditions which require monitoring of dietary intakes should be under the management of health care professionals and checking food labels regularly, as product composition can change without warning irrespective of having a specific reformulation program in place, and adjusting their dietary intake and/or medication accordingly.

To minimise the effect on the small numbers of people with specific dietary needs, the PRP will incorporate clear messaging and education about the nutrients and food categories recommended for reformulation to consumers and health professionals.

General Risks

3.15 Technical feasibility

Comments in submissions

- Target may not be technically feasible / possible.
- General comments were made in relation to the time needed to work out how to technically implement the change, in a business and consumer acceptable way.

Risk Assessment

Despite 'best efforts' by the RWG there is a small risk that implementation may bring to light the fact that a set target is not feasible. The likelihood of this is considered to be low, or relevant to only a few product types in a given reformulation food category. The intent of the PRP is reformulation, not new product development – where the target cannot be reached without so significantly changing the product that it would be considered a different new product, then reformulation is encouraged to the extent possible.

In developing the draft targets, the RWG considered food category definitions in which products were reasonably similar or used similar production methods (e.g. savoury pastries). Consideration was also given to existing products in the market within each nominated food category that already meet the sodium target; and to international targets both of which again give some indication of technical feasibility. It is noted that some of the UK's reformulation targets are more stringent. In the case of sugar this was at times deliberately so, with the idea that reformulation targets may help to drive technological innovation. The Australian PRP has not taken that approach.

The RWG draws a distinction between what is technically feasible (e.g. product will not fall apart if reformulated to the level set), business decisions (e.g. not to reformulate marque products), or capacity limitations (not enough food category specialists within a company to reformulate all products in a category at once, or very large product portfolio in a given category). Business decisions or capacity limitations should not preclude a target begin set, but may be considered in the implementation approach (e.g. timeframe).

The four year timeframe is considered adequate for undertaking one or several incremental rounds of reformulation including acceptability testing, packaging and labelling changes. If there is evidence through reporting during the implementation period that capacity is the limiting factor, implementation timeframes may be reviewed on a category basis.

Reformulation that is not technically feasible due to food safety issues should not be conducted if the risks cannot be adequately managed, with relevant information relayed to the Healthy Food Partnership's Executive Committee.

3.16 Data validity; targets have been developed using old data.

Comments in submissions

- Data used is over 6 years old (AHS and NNPAS data) – retail and food service landscape significantly different across this timeframe.

Risk Assessment

While the food consumption data is six years old, it is the best available data for this purpose, excluding industry sales-weighted data which is prohibitively expensive to purchase over so many categories. Categories will be assessed against new consumption data if/when it becomes available.

The information on the ranges of nutrient content in products within nominated food categories (minimum, maximum, median and mean for each category) was derived from the most recent (2016 or 2017, whichever was the most recent complete collection) food label data held in the FoodTrack™ database[(11)], reflecting more up to date information on products available in the market place. These ranges were used to assist in identifying appropriate targets for sodium, saturated fat and sugars content for each food category. The RWG also checked their data set and targets against data from FoodSwitch, provided by The George Institute as part of their submission to the consultation, and found it to be comparable.

AHS and NNPAS data were used to determine key categories which contribute to total dietary intake. Newer consumption data may have identified a few additional categories, but the RWG is satisfied that a broad range of food product categories are captured in the PRP.

The food categories identified are amongst the main contributors to population intake of the three identified risk-associated nutrients, according to data collected under the NNPAS in 2011-12; however it is recognised that food categories and consumption patterns are constantly changing. In addition to the identified categories, manufacturers may consider reformulating their high sales volume products. As an example, whilst not identified in the current set of targets, the category of 'dips' is one identified as a high growth area with some high sodium products [refer to AUSNUT 2011-13][(27)]. While no reformulation target has been set for these products, manufacturers could be encouraged consider reformulating products with sales volumes that may result in significant contributions to a reduction of sodium intakes.

Reformulation targets should also be applied to new product development within the defined categories.

In addition, the establishment of these reformulation targets should not restrict industry from efforts to reformulate products that are currently out of scope wherever possible, consistent with the reformulation policy objectives outlined in this document.

3.17 Reformulation is not the complete solution

Comments in submissions

- Consumer education campaigns should also compliment such initiatives. We can and will reduce the salt levels in our products, however, without consumer education this might not lead to a lower salt intake as consumers might add extra salt back themselves.
- Public education: in order to support consumer uptake of reformulated products in the market, the PRP MUST be combined with effective public health education on nutritious food choices aligned to ADGs, in addition to education on reading food labels. Reformulation could consider the addition of positive nutrients, where permitted by the Australian New Zealand Food Standards Code, rather than focusing only on the reduction of risk-associated nutrients.

Risk Assessment
The RWG has always acknowledged that reformulation is not the complete solution, and for this reason it is just one of the streams of work being progressed under the Healthy Food Partnership.

Communication activities have commenced, and will continue to build with messages tailored to the target audience and using various channels (such as website, social media, POS flyers, fact sheets, industry newsletters).

The Healthy Food Partnership's Executive Committee; Implementation, Monitoring and Evaluation Reference Group; and the Department of Health will work together to identify and meet communication needs and opportunities related to reformulation and broader Healthy Food Partnership work.

3.18 Concerns regarding consumer choice, commercial viability, reduced competition and product innovation.

Comments in submissions
- Is important that reformulation does not lead to further reductions due to a fewer products being available to consumers that meet their preferences.
- Investments in reformulation activities should not be to the detriment of commercial viability, consumer acceptance or shelf-life stability that could reduce the range and variety of options available.
- Australians must have access to a variety of product types that meet their needs and preferences so that they can enjoy a wide variety of nutritious foods.
- Mandatory nutrient reformulation for whole categories of food can reduce competition and innovation in the food supply.

Risk Assessment
In determining the reformulation targets, the RWG reviewed existing product data, which showed that there are existing products with nutritional profiles that are below the proposed targets. This indicates that products that meet the targets are acceptable to consumers, as well as demonstrating that products can be viable and have adequate shelf life with salt, saturated fat and sugar levels at and below the proposed targets.

In addition, the PRP will have an implementation period of 4 years, which will allow companies to make changes over time, and for consumers to gradually adjust to lower salt, saturated fat and sugar levels.

It is considered unlikely that the PRP would prevent companies from innovating, as products already exist with salt, saturated fat and sugar levels at and below the proposed target, and innovation can occur within the new parameters.

3.19 Criticism from industry - Failure to recognise past efforts, partial work, work in progress; or instances of technical impossibility.

Comments in submissions
- Negative perception, irrespective of progress, if some products either cannot meet the target in the set time-frame because of the time taken to achieve an acceptable [sodium] reduced product or prioritising other products.

- Negative public relations for industry: Previous campaigns (eg: Unpack the Salt, George Institute/AWASH campaigns) have named and shamed specific industry brands and products for nutritional content, there needs to be an agreement between the RWG and industry around communications of efforts. For example, commitments and progress of reformulation should be recognised and promoted, rather than negative communications and disregard of positive progress.
- Unable to reformulate 100% of portfolio products (timeframes, unknown technical challenges, use saltier ingredients (e.g. salted caramel flavour, ACCC provisions around naming of foods as 'salt' flavour and matching consumer expectation of the characterising ingredient).

Risk Assessment

Ideally the PRP would see 100% of relevant in scope products reformulated so that sodium content is reduced to the target set for maximum levels within the implementation period.
In practice it may be more pragmatic to aim for 90 – 95% of products in each category portfolio on a sales-weighted basis. Evaluation of this will rely on accurate industry reporting, as sales weighted data is prohibitively expensive. The UK and NZ similarly have a % reduction target. This makes allowance for products a very long way from the target, products where partial reformulation is possible but implementing the target completely makes product non-viable (e.g. falls apart) without having to define every inclusion and exclusion on a category basis.

The RWG has further considered sub-category targets for products with 'salted' flavour profiles / product name and for products with high sodium characterising ingredients (e.g meat pizza, chicken cordon bleu) in the context of feedback received during the consultation on individual food category definitions and targets.

While it may take some time for the RWG to finalise all recommendations for the PRP, and there is industry awareness of the development of targets in Australia as well as international reformulation programs, not least in New Zealand; and recognising the trans-Tasman food system, it may be appropriate to set the baseline for monitoring and evaluation purposes based on 2018 data. An early decision on this would give some certainty to industry, however as maximum target levels rather than percentage reduction are proposed for the majority of categories, the effect of this on industry's ability to meet targets may be irrelevant. It is relevant to industry ability to report own reductions as percentage of total content, progress made if target not yet achieved / achievable (e.g. reduced by 20% towards the target), or amount of sodium removed from products / food supply annually.

3.20 Misalignment with various international and domestic targets (reformulation, canteen guidelines etc.). Imported products do not need to comply, creating an uneven playing field

Comments in submissions

- Products made in New Zealand, or sold in both countries may already be working towards the New Zealand Heart Foundation reformulation targets.
- Comments more generally about targets not aligned with state canteen guidelines, healthy eating policies, international targets
- Imported products would not be captured / would not need to adhere to the targets. Reformulation is likely to impact Australian made products more than imported products.

Risk Assessment

The RWG has reviewed the targets in light of the New Zealand Heart Foundation reformulation targets and, where appropriate, have taken steps to align these. However, the RWG determined the targets after giving consideration to the products available in the Australian food supply and consumption patterns of the Australian population. In some instances, the product range in Australia is not comparable with the range available in New Zealand.

The RWG acknowledges that imported products are not targeted by the PRP, but does not believe that the small numbers of imported products will significant impact Australian businesses.

3.21 Financial costs to industry

Comments in submissions

- Reformulation requires significant resource and many associated costs – such as technical resource time, research and trials, label updates, analytical tests (particularly when effects of major changes on food safety are unknown). Such costs fall to food industry and can be extremely costly – up to $10,000 per SKU. These costs would be in addition to recent costs industry has had to bear with label updates for Country of Origin and HSR. A more realistic approach could be manufacturers committing to a proportion of their portfolio to be reformulated within the four year target – with a view for further formulation post this date.
- Resources and costs for label change(s) on top of Country of Origin Labelling (CoOL) and HSR recent changes

Risk Assessment

The cost to industry of product reformulation, testing, composition analysis and changes to packaging etc. is acknowledged, including in the context of other labelling changes such as HSR and CoOL introduced over the last five years.

The four year timeframe proposed is reflective of other food system changes in recent years, including the HSR system, CoOL labelling requirements and the previous Food and Health Dialogue target implementation periods. Within this period companies may make incremental changes or a single (larger) change. Incremental changes will necessitate multiple rounds of testing and label changes so compounds the costs to industry.

In relation to the HSR system, Ministers agreed to a five year implementation period in order to enable cost effective implementation and the potential for food reformulation and consultation with small and medium sized enterprises. This decision was informed by a cost benefit analysis prepared by PricewaterhouseCoopers which explores the cost borne by industry, governments and non-government organisations and the potential benefits to public health with the voluntary introduction of the HSR, and the findings of an independent qualitative study by the Centre for International Economics on the impact of the HSR system for small business.

The PRP is different to HSR in that product reformulation is required before a labelling change would be made (HSR was a labelling change only, although anecdotally some companies chose to reformulate before labelling); but a proportion of the portfolio may already meet the target, so 100% compliance may not require 100% of products to be reformulated.

Previous voluntary Food and Health Dialogue targets were set with 3-4yr implementation periods, and a baseline for comparison generally 6-12 months earlier than commencement (the cheese baseline was almost two years earlier than commencement of the target)

Mandatory CoOL provisions were implemented with a two year transition period.

Healthy Food Partnership's Executive Committee requested that the RWG look for 'quick wins'. If targets are ratified and commence at different times, this will have the effect of spreading the total PRP (and associated costs to industry) over a longer period even if 4year implementation periods are recommended for all.

Burden to industry may be lessened by:

- Setting baseline at 2017 - relevant to targets with % reduction only; maximum level targets will not benefit from an earlier baseline other than if the target is not met, there is a (potentially) more positive story to tell about the level of change which has been achieved.
- Setting two stages of reformulation target (moves whole category incrementally and together). However this will also then require at least two rounds of reformulation and changes and will likely shift the extreme end of products first.
- Specifying a compliance rate that is less than 100%, e.g. deemed to comply if 95% or portfolio for category meet the target and efforts have been made to reduce the remaining 5%.

3.22 Uneven playing field relative to food service products - Target is food at the retail level; food service products are not targeted for reformulation.

Comments in submissions

- Lower sodium products are more acceptable within the retail sector than foodservice. Reformulated products used in food service may be deemed insufficiently salty, food establishments and/or customers might add table salt to the product once prepared, thereby negating the reformulation work of industry. This highlights the need for education within foodservice (e.g. for chefs) which has been lacking.

Risk Assessment

There is limited available data about nutrient levels consumed through food service items, and so the RWG has relied on FoodTrack™ (retail) data and the Australian Health Survey in determining draft targets. As a first step, the focus of the PRP at the current time is on foods sold at a retail level. This focus on retail does not preclude manufacturers of food service products from committing to targets, or to reformulation with respect to reducing saturated fats, sodium and sugar content of foods offered for purchase more generally. This is in fact encouraged. Furthermore, some products sold through food service outlets may benefit from the reformulation targets and experience changes to their formulation as a result of them - e.g. pizza in the food service setting will have reduced sodium if the component ingredients of processed meats, cheese, and sauces have been reformulated to meet sodium targets.

There is opportunity to recognise reformulation efforts through PRP reporting and through the Healthy Food Partnership's Food Service Pledge Scheme, wherein retailers, canteens etc. can pledge to purchase and supply reformulated, lower sodium/ added sugars / sat fat products; manufacturers can pledge to conduct reformulation, and supply chain partners can clearly identify healthier options in supply lists / ordering systems.

Reducing sodium levels in comparable products at retail and food service outlets may assist to lower the consumer palate for saltiness. Population-level, consumer awareness activities about the Healthy Food Partnership activities and benefits of consuming a diet lower in sodium are intended to help to provide consumer understanding that the changes are being made for a health benefit. Communication materials under the Food Service Pledge Scheme may also provide more specific information to kitchen staff and customers about actions of particular food businesses to reduce the sodium, added sugars and/or saturated fats content in foods offered.

The reformulation targets were determined at the retail level, but can be encouraged in food service environments. There may be some natural cross over where the same product is supplied to food service as that in retail, or with manufacturers committing to reformulation in line with the targets even though food sold at food service outlets are not the primary target. Voluntary reformulation across retail and food service products can be supported through positive and specific communication activities.

Communication activities of the Healthy Food Partnership, and particularly in relation to the PRP and Pledge Scheme should reiterate that nutrient reformulation targets are primarily developed for products at the retail level; but note opportunities for cross-over into the food service environment:

- Same product sold as in retail could be a priority for reformulation
- Communication to food service businesses about looking /asking for reformulated products, {to enable them to meet pledges}
- Communication to manufacturers of food service products, sold into the food service pathway, that they may wish to consider working towards the targets
- Communication to consumers about 'taste your meal before adding salt' and ways to eat more healthily at home and when out.
- Communication materials directed at food services: industry is working to create great tasting, healthier products suitable for the food services.
- Leverage state initiatives in the food services, e.g. Healthier Choices Canberra (ACT), Healthy kids (SA)

4. Discussion and Conclusion

Addressing the rising rates of overweight and obesity in Australia is a complex problem and will require multiple strategies to prevent further rate increases. There is a substantive body of scientific evidence supporting the ADGs to reduce intake of foods high in saturated fat saturated fat, added salt and added sugars, and to select mostly reduced fat dairy products. The PRP, with a focus on reducing saturated fat, sodium and added sugars content through reformulation, is one of the strategies intended to contribute to the improving the health status of the population. Proposed nutrient content targets are intended to be in line with the ADGs, and it is recommended that consumer messaging about consumption patterns that align with the ADGs continues and increases.

Manufacturers retain flexibility to implement the PRP to meet the nutrient targets in a way that is technically feasible for their products while retaining the nature of the product. Reformulation that is not technically feasible due to food safety issues should not be conducted if the risks cannot be adequately managed, with relevant information relayed to the Healthy Food Partnership's Executive Committee.

Future health surveys and updates to food composition databases will be an important part of monitoring the impact of the PRP and re-evaluating the reformulation targets and scope as required. Although it should be noted that it is unlikely to be a clear causality for any changes.

Based on this assessment, the risks raised do not preclude the PRP from progressing.

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