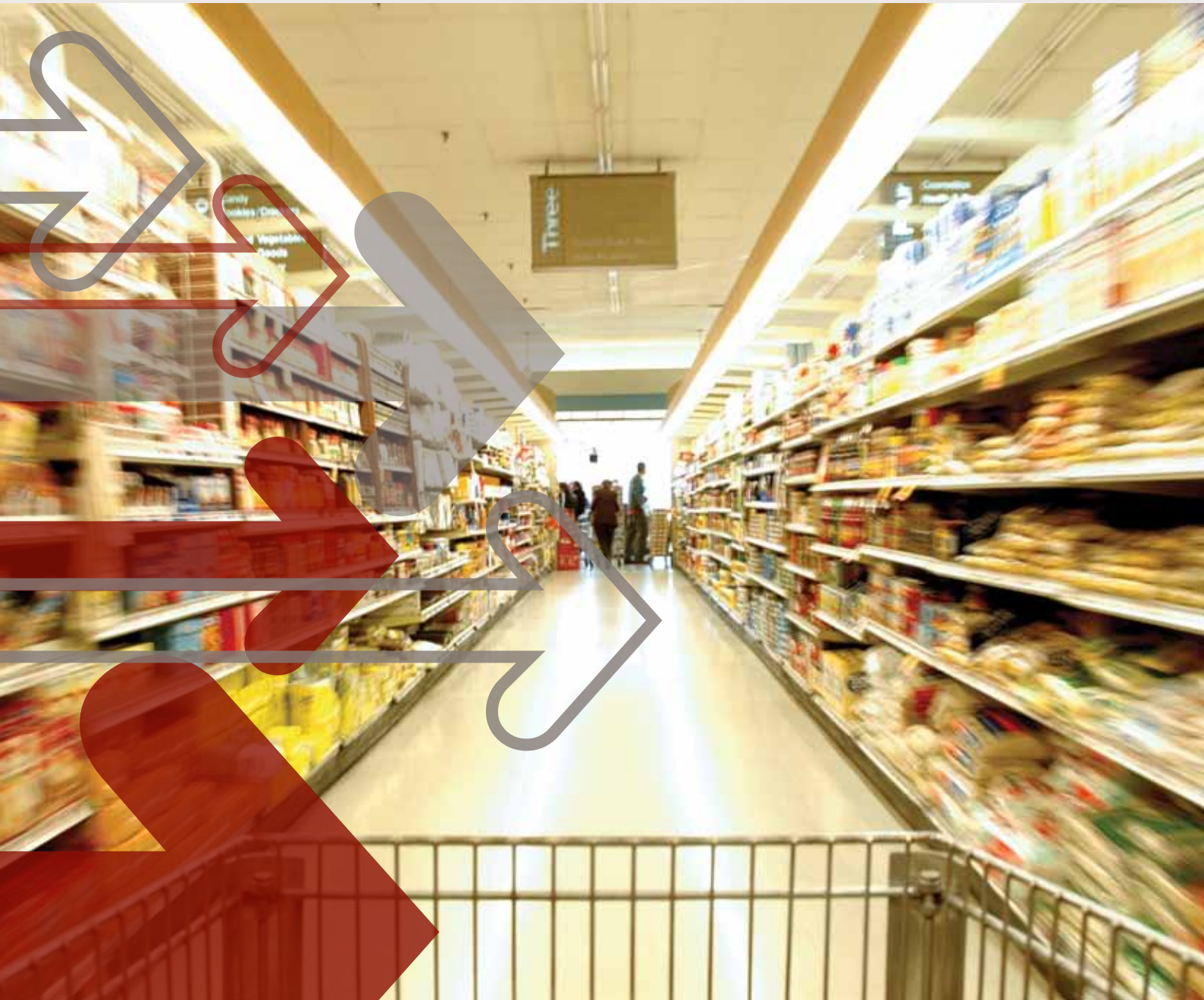
Heart Foundation®

Rapid review of the evidence

Effectiveness of food reformulation as a strategy to improve population health



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About this paper

This rapid review presents literature on the effectiveness of reformulating commonly consumed processed foods as a way of improving dietary intakes and population health, with a particular emphasis on cardiovascular outcomes.

The Heart Foundation defines reformulation *as changing the nutrient content of a processed food product to either reduce the content of negative nutrients such as sodium, saturated fat, trans fat or energy (kilojoules) or to increase the content of beneficial nutrients such as dietary fibre, wholegrains, fruit, vegetables and unsaturated fats*. The definition does not include the addition of vitamins, minerals or nutrients through fortification processes.

Specifically, this review sets out to describe the evidence on:

- the health and economic impact of food reformulation initiatives
- key components of successful food reformulation programs.

PubMed, ScienceDirect, CINAHL, Medline, Cochrane, InformIT and Google were used to search literature published up until April 2012. Studies were limited to those published in English. The search strategy focused on peer-reviewed original research, and grey literature including government and non-government reports, case studies, position statements and media articles.

Search terms varied between databases. 'Food reform*' or 'food reformul*' were used in all databases, with 'food industry' as a MeSH term together with free text terms 'nutrients' and 'food' and 'benefit' or 'impact' or 'health' or 'enhance' or 'improve' in the title/abstract. Other free text terms included 'food policy', 'food reform', 'food safety' or 'economic'. Relevant articles identified in reference lists were also traced. This review focused on the effectiveness of processed foods available in the retail sector and has excluded studies looking at reformulation in the quick service restaurant (QSR) setting.

A total of 287 articles were found and 123 deemed relevant for inclusion in the rapid review. Using a rapid review approach to describe the evidence, each article was summarised and then categorised into themes as seen in Tables 1 to 4.

While randomised controlled trials are regarded as the highest level of evidence, they are often unsuitable (and even unethical) in free-living contexts where many public health interventions take place. Most studies in this review were observational studies, cost analyses, data and scenario modelling, peer-reviewed commentary and non-peer reviewed reports.

Unlike a systematic review, this review has used an abbreviated appraisal process. Evidence levels have not been assigned to individual studies. However, potential biases and limitations have been considered prior to making any recommendations. As a description of the evidence base, it aims to support policy makers in their decision-making and provides a basis for future research and evidence reviews.

Background

Good nutrition is the cornerstone of health and plays a pivotal role in the prevention of chronic disease.

A diet rich in wholegrains, vegetables and fruit; and low in saturated fat, trans fat and sodium protects against many of today's so-called 'lifestyle' diseases (cardiovascular disease, type 2 diabetes, obesity and some cancers). There is scope to improve Australian diets with dietary risk factors now accounting for approximately 16% of the disease burden.[1,2]

Hypertension alone is responsible for 7.6% of this disease burden, while overweight and obesity accounts for 7.5% and elevated cholesterol for 6.2% of the burden.[3] These risk factors are all strongly associated with diet.

The role of sodium (from dietary salt intake) in the development of hypertension and stroke is well established.[4-11] There is also good evidence documenting the association between cholesterol profiles and intake of saturated and trans fats.[12-19] Dietary energy (kilojoule) intake is a critical component in maintaining a healthy weight. Energy consumed in excess of an individual's requirements can contribute to the development of overweight and obesity.[20]

The impact of these dietary risk factors has been acknowledged by health organisations around the world. In 2003, the World Health Organization (WHO) proposed nutrient targets for the international community to help improve dietary intakes in populations to reduce chronic disease risk.[21] These daily targets are as follows:

- upper limit of 2000 mg for sodium (5 g salt)
- 10% of dietary energy intake from saturated fat
- 1% of dietary energy intake from trans fat.

In Australia, the National Health and Medical Research Council has set an upper limit of 2300 mg/day for sodium (almost 6 g salt) and recommends that intake of trans and saturated fat (combined) be less than 8–10% of total energy.[22]

When released, data from the Australian Health Survey (2011–2013) will provide a comprehensive picture of Australian population dietary intakes and food trends.

Until such time, the 1995 National Nutrition Survey and other sub-population surveys must be relied upon to gauge how far Australia is from achieving the above targets. It is estimated that the average salt intake of Australian adults is approximately 7–12 g/day or 2,800–4,800 mg sodium (about the same as it was 10 years ago).[23-26] The majority of dietary sodium (75–80%) comes from processed foods such as breads, breakfast cereals, processed meats, cheese, sauces and spreads.[27] Only 15% comes from using salt in cooking or at the table.[28] Evidence suggests that Australian intakes of trans fats have declined and are below the WHO's recommendation.[29] However, we are still obtaining around 14–16% of total daily kilojoules from trans fats and saturated fats combined. This is above the Australian recommendations.[30] In 1995, the greatest contributors to saturated fat in the Australian diet were milk, cheese, pastries and frozen milk products (e.g. ice-cream).[31]

> Interventions that go beyond individuals' knowledge and 'freedom to choose' are needed if we are to effectively address poor nutrition and lifestyle diseases.

Achieving dietary improvements at a population level has been a perennial concern for public health professionals and health departments. Over the past two or three decades, public health programs have focused on changing individual behaviour through social marketing campaigns, community-based interventions and primary healthcare education. These have met with varied success. Often resource-intensive, they have been short-term interventions and at best provide an indication of short-term impacts only.[32] Furthermore, a Cochrane review in 2004 demonstrated that improving diets on an individual basis is notoriously difficult and largely ineffective in the long term.[33] Many argue that dietary education in isolation is ineffective because personal responsibility for food choices has been removed from the consumer, with unhealthy foods becoming more ubiquitous and affordable.[34-36]

Interventions that go beyond individuals' knowledge and 'freedom to choose' are needed if we are to effectively address poor nutrition and lifestyle diseases.[32,33,37] To this end, the Heart Foundation Tick Program has been working with food manufacturers in Australia since 1989 to improve the nutrient profile of processed foods.[38,39] In recommending a wide variety of foods, the Heart Foundation recognises that processed foods are often a prominent feature in the Australian diet. Processed foods now account for approximately 75% of total food sales.[40] Supermarket shelves in Australia contain around 40,000–55,000 individual

food products, many of which are processed foods.[36,41-43] The extent to which foods are processed varies greatly from product to product. Some foods are extensively processed (or ultra-processed). Ultra-processed foods refers to those non-core foods such as confectionery, chocolate, crisps and soft drinks, but also includes many everyday foods such as bread, biscuits, breakfast cereals, soups, sauces, cheese, pre-prepared meals and processed meats.[44] Ultra-processed foods often contribute unnecessary amounts of sodium, saturated fat, trans fat and energy to the diet.[44,45]

The WHO and key advocacy agencies (such as the World Action on Salt and Health (WASH) and the Australian Division of World Action on Salt and Health (AWASH)) have called on food manufacturers to reduce the sodium, total fat, saturated fat, trans fat and energy in their products.[21,46-55]

The public health challenge is to work with the industry to commit to delivering both a healthy and economically productive food supply. Australia's food manufacturing sector makes a significant contribution to the Australian economy.[56] A competitive and productive food industry is clearly important, but it cannot be at the expense of population health.[57]

To facilitate industry-wide improvements, the Commonwealth Department of Health and Ageing established the Food and Health Dialogue in 2009. This is a non-regulatory platform of collaboration between government, public health experts and the food industry.[58] Its objective is to facilitate food innovation in delivering healthy choices by reducing saturated fat, sodium, added sugar and energy, and increasing the fibre, wholegrain, fruit and vegetable content across nominated food categories.[58] It includes a voluntary reformulation program targeting a range of commonly consumed foods. Reformulation targets are balanced against the technical and safety constraints faced by food manufacturers. Targets have already been set for bread, breakfast cereal, processed meat, simmer sauce and soups. It is anticipated that reformulation targets for savoury pies and pastries, processed poultry and cheese will be set in 2012. Once the Dialogue sets the nutrient target for each product category, the onus is on food

manufacturers to elect which product/s they reformulate to meet this target. A comprehensive and robust evaluation strategy is required to determine the progress of voluntary reformulation efforts. The government plans to support the Dialogue's reformulation program with activities (where appropriate) aimed at reducing and standardising portion sizes and educating consumers on healthier food choices.[59]

For some food manufacturers in Australia, food reformulation represents a new challenge. For others, it has been an ongoing commitment. Formulating new products with healthier profiles is to be commended, but this needs to happen alongside reformulation of existing products to reduce consumer confusion and to shift taste preferences incrementally.[42,60]

With a sophisticated food industry and a federal government commitment to delivering healthier choices, Australia is well placed to lead the world in a meaningful food reformulation program. It is hoped that this review will assist policy makers in setting (and reviewing) the reformulation agenda. It will be a valuable tool for the Australian food industry, food retailers, public health professionals and engaged consumers in working towards a healthier food supply.

Evidence highlights

This review builds on the evidence highlighting reformulation as a critical element in achieving population nutrient goals consistent with prevention of chronic disease.[37,44,54,55,61-75]

Reformulation of processed foods provides a realistic opportunity to improve the health of a population through improving the nutritional characteristics of commonly consumed processed foods. Further, food reformulation has the potential to reduce absolute health inequalities, with disadvantaged groups likely to benefit proportionately more than the general population.[76-80]

Reformulation of processed foods provides a realistic opportunity to improve the health of a population.

The literature identified a variety of initiatives in place or planned, often in tandem with front-of-pack (FOP) labelling, mandatory nutrition labelling and social marketing campaigns to promote demand for healthier products.[38,39,48,50,51,61,64,67,68,70-72,74,81-112] Many of these initiatives, described in Table 1, have documented the impact of food reformulation in terms of improvements to the food supply.[38,64,65,72,85,88,89,91,98,99,106,109] Removal of sodium from specific product categories was the primary achievement, with some studies also reporting on saturated fat and trans fat reduction. The Heart Foundation Tick Program in Australia has demonstrated the food supply impact that results from the efforts of just one food company. Over a one-year period, this company saw a 235 tonne reduction in salt from reformulating the sodium content of 12 of its breakfast cereal products.[106] Additionally, 9,622 tonnes of saturated fat and 3,465 tonnes of salt were removed over an eight-year period from leading margarine products as a result of two companies committing to the program.[39] Similar achievements have been demonstrated by the New Zealand Heart Foundation Tick Program and the Canadian Health Check Program, as outlined in Table 1.

The Food Standards Agency (FSA)'s salt reduction program in the United Kingdom (UK) brought about significant improvements to the food supply as well as population sodium intake.[74] The FSA program involved reformulation of the sodium content of processed foods and a voluntary FOP labelling system (beginning in 2006). This was underpinned by a public awareness campaign that commenced in 2004. Private label brands demonstrated an average reduction in salt of 30% in sliced bread and 49% in breakfast cereals. Most importantly, the FSA program was able to demonstrate a 0.9 g reduction in UK population salt intakes.[88,113] This reduction is assumed to be a direct result of the efforts across the manufacturing and retail sectors to reformulate products, coupled with changes in consumer dietary practices.[74] More recent literature has revealed that average population salt intake in adults has fallen by approximately 1.5 g/day since the commencement of the FSA program.[114,115] France also demonstrated a 0.4 g/day reduction in average population salt intake over five years, corresponding with reformulation and consumer awareness campaigns.[72]

Fewer reformulation programs have been evaluated in terms of their impact on health outcomes. Evaluating the population impact of specific reformulation initiatives is especially difficult if there are concurrent public health strategies in place. Additionally, the multifactorial and distal nature of chronic disease adds another layer of complexity to measurement. Some studies, outlined in Table 1, have demonstrated change in population intake but have not attributed these to observed disease rates in the same time period.[64,98] Others have modelled the expected health outcomes based on the measured impact on the food supply or population intake.[37,72,116] The best available evidence of effectiveness (in terms of health outcomes) is drawn from the Finnish experience with sodium reduction and the Mauritian initiative in reducing saturated fat.

In Finland, a 3 g salt reduction in average intake between 1979 and 2002 was achieved through reformulation of processed foods, mandatory sodium labelling and a sustained public awareness campaign.[92,117-119] During the same time period, a reduction in both diastolic and systolic blood pressure was observed (as measured by an average reduction of 10 mmHg in the population) and a 60–80% reduction in stroke and cardiovascular disease (CVD) mortality occurred.[92,117,120,121] While concurrent primary prevention strategies were in place in Finland during this time, the fall in blood pressure has been attributed to the dramatic decrease in salt intake.[92]

In Mauritius, a government-led intervention over five years to replace palm oil with soybean oil as the common cooking oil saw a 3.5% decrease in energy intake from saturated fat, a 5.5% increase from polyunsaturated fat and a 0.79–0.82 mmol/L reduction in average adult total cholesterol concentrations.[104] A WHO systematic review of 261 diet and physical activity interventions has classified the Mauritian example as one of only three effective policy and environment strategies to improve population health.[32]

Given the challenges associated with evaluating reformulation, many studies have sought to predict the cardiovascular health gains and cost-effectiveness of population nutrient intake through dietary modelling. These are detailed in Table 2. There is abundant information exploring the health and economic benefits of reducing sodium consumption,[37,76,77,91,122-124] with fewer studies looking at saturated[89] and trans fat.[125] Little or no information was found for nutrients such as added sugars,[67] fibre, wholegrains, fruit, vegetables or calcium. In Australia, there are substantial health gains to be achieved if sodium in processed foods is reduced by 15–25% over 10 years. This achievement could prevent 5,800 to 9,700 heart attacks and 4,900 to 8,200 strokes from occurring in Australia in one year.[62] Another Australian study estimated that a mandatory reformulation program reducing sodium content of all bread, margarine and cereal products in line with Heart Foundation Tick criteria would avert 18% of the burden of disease associated with excess dietary salt consumption.[37] Modelling in the United States (US), UK, Norway and Canada has consistently demonstrated the substantial population health gains possible from reduced population sodium intake.[76,77,122-124]

Not only do population-wide approaches (such as food reformulation) appear to be effective in reducing cardiovascular risk, studies have also demonstrated the cost-effectiveness of such strategies.[37,71,76,77,122-124,126,127] These have been described in Table 3. Modest investments in food reformulation have the potential to generate significant public sector cost-savings. For example, the UK FSA invested £15 million on the salt reduction program; an investment estimated to prevent 6,000 cardiovascular deaths per year and save approximately £300 million a year.[76] A US study estimated that a regulatory food reformulation intervention reducing US population salt intake by 3 g per day (the minimum amount needed to reach the WHO sodium target in Australia) would achieve the same population-wide cardiovascular health benefits as that achieved from a 50% reduction in population smoking rates, or a 5% reduction in body mass index (BMI). The estimated health savings would be US$10 billion to $24 billion per year. Even if a 1 g/day reduction was achieved incrementally over a 10-year period, such an intervention would still be significantly more cost-effective than using medications to lower blood pressure in people with hypertension.[77] A reduction of 3 g/day in population salt intake appears to be an entirely feasible goal for governments, given the 3 g/day reduction achieved in Finland where food industry resistance was strong and cultural food tastes are deeply entrenched.[76,128]

From the literature describing reformulation initiatives, and building upon the important work already done in the area,[64,70-72,80] common themes emerged that provide the backbone for our recommendations in supporting a comprehensive and effective reformulation program in Australia. This evidence is summarised in Table 4.

The complexity of reformulating processed foods has been well documented in the literature. A collaborative approach between government, industry, researchers and public health bodies will help address the challenges associated with improving the nutritional characteristics of processed foods. Each product category needs careful consideration of the technical and taste elements of reducing unnecessary salt, saturated and trans fat.[71,84,90,101,129-140] Lessons from established reformulation programs indicate that criteria should be category-specific and adopt a multi-nutrient approach. This will address the interplay of nutrients within foods, and minimise costs related to packaging and product development.[12,70,71,88,89,107,108,136,141] Priority should be given to reformulating products that contribute the most to population intake of selected nutrients.[70,101,132]

To be successful in shifting population tastes and maintaining consumer acceptance, progressive, incremental change is strongly supported.[71,132,142,143] This is consistent with evidence that suggests that a preference for dietary salt can be adapted and lowered following reductions in sodium content of the diet over a period of time.[144,145] This reduction can be achieved through modest, sequential reductions over a relatively short period, even as little as six weeks.[146] Incremental change can also be used for other nutrients such as fibre, wholegrains, sugar and replacing saturated fat or trans fat with unsaturated fat.[142]

The literature identified the need for an approach that brings together the agricultural, manufacturing, processing and retail sectors.[101,107,108,136,141,147] In any reformulation initiative, high-level leadership has been shown to elicit better stakeholder engagement.[64,71,72,85] Reformulation programs should be part of a multi-level strategy, led by government to improve population nutrition.[71,72,85] Reformulation approaches that feature consumer awareness campaigns and FOP labelling have also demonstrated clear and substantial health outcomes.[71,105,147] The nutrient criteria of interpretive FOP labelling and mandatory nutrient labelling has encouraged reformulation in Australia, Canada, Finland, New Zealand, the Netherlands, Sweden, the US and UK.[68,70,71,95,98,105,106,109,119,147]

Monitoring and evaluation of the food supply, dietary intake, health gains and economic benefits are critical to building the evidence base for reformulation.[71,72,80,105,148] While literature on the impact on population dietary intake and food supply was available, this rapid review identified only two studies linking population level strategies with health outcomes among the 21 initiatives identified.

Ultimately, a mandatory approach to reformulating processed foods has been shown to significantly shift a population's intake of sodium, saturated fat and trans fat from commonly consumed, processed foods.[37,50,61,77,79,123] While most initiatives depended on voluntary reformulation action, the evidence demonstrates that greater outcomes are possible from legislating such initiatives.[37,79,127] Australian modelling has shown that the impact from implementing mandatory sodium reformulation is 20 times greater than the health gains possible from a voluntary reformulation incentive program.[37]

This review has highlighted the achievements that have been made from voluntary approaches to reformulation, and this may be an appropriate starting point. However, it is clear from the evidence that the potential health gains are much greater from a legislated approach, led by government, and engaged with industry, the public health sector, non-government organisations and consumers to ensure population nutrient targets are met.

Table 1: Studies relating to food reformulation initiatives

Impact on the food supply

Findings	Study type
• There are many examples of reformulation achievements demonstrating food supply impact through measuring the removal of sodium, saturated fat and trans fat and added sugars from specific product categories.[38,39,64,65,72,81,85,88,89,91,98,99,106,108-110]	Non-peer reviewed report[39,81,85,88,89,91,110] Peer-reviewed article[38,64,72,99,106,108,109] Peer-reviewed commentary[65] Peer-reviewed analysis[98]
• The Australian Heart Foundation's and the New Zealand Heart Foundation's respective Tick Programs have demonstrated reduction of sodium and trans fat from commonly consumed products such as bread, breakfast cereals, sauces, processed meats, soups and margarines.[38,39,106,109] o The Australian Tick Program demonstrated a 235 tonne reduction of salt in the food supply in a one-year period in 1997 through the efforts of one food company in one product category alone.[106] o Additionally, 9,622 tonnes of saturated fat and 3,465 tonnes of salt were removed over an eight-year period from leading margarine products as a result of two companies committing to the program.[39] o The New Zealand Tick Program has demonstrated a reduction of approximately 33 tonnes of salt in the food supply in a one-year period.[109]	Peer-reviewed article[38,106,109] Non-peer reviewed report[39]
• The Canadian Health Choices Program, similar in concept to the Australian and New Zealand Tick Programs, estimated that 805 tonnes of salt has been removed from the food supply over four years through the reformulation or formulation of a variety of products across several categories.[110]	Peer-reviewed article[110]

Impact on population dietary intake

Findings	Study type
• The 0.9 g reduction in salt intake (360 mg sodium) of the United Kingdom population between 2001 and 2008 is attributed to the reformulation of products and consumer awareness campaigns.[72,74,85,88,113] • More recent literature indicated that since the commencement of the Food Standards Agency's program, salt intake in adults has fallen from 9.5 g to 8.1 g per day (i.e. approximately 1.5 g per person, per day).[114,115]	Peer-reviewed article[72,74] Sampling survey[113] Non-peer reviewed report[85,88,115] Media release[114]
• Replacement of palm oil with soya bean oil as the commonly used cooking oil in Mauritius demonstrated a 3.5% decrease in energy intake from saturated fat and a 5.5% increase in energy intake from polyunsaturated fat intake in the adult population between 1987 and 1992.[104]	Cross-sectional survey[104]

Impact on population dietary intake *continued*

Findings	Study type
• Finland introduced a voluntary sodium reduction program from the late 1970s, incorporating food reformulation, consumer education and warning labels on high salt foods. o Between 1978 and 2002, average population salt intake decreased by around 3 g/day (1,200 mg sodium), which was calculated to be an age-adjusted annual reduction in salt intake of 0.14 g (56 mg sodium).[72,117,118] o In men in the North Karelia region, salt reduction was reduced from 12.9 g per day (95% CI 12.4 to 13.5) in 1979 to 9.5 g per day (95% CI 8.9 to 10.0) in 2002.[118] o The age-adjusted annual reduction in salt intake was 0.14 g (56 mg sodium) ($p < 0.001$).[118]	Peer-reviewed article[72,117] Cross-sectional population survey[118]
• In France, a decline in average dietary salt intake of 0.4 g per person per day (160 mg sodium) from 8.1 to 7.7 g/day in the adult population has been observed in parallel with reformulation and consumer awareness strategies.[72]	Peer-reviewed article[72]
• Average population intake of trans fat in Canada has reduced by 30% between 2004 and 2008, from 4.87 to 3.44 g/day or 2% of total energy (E) to 1.4% E as a result of 76% of identified foods reformulated to reduce trans fat.[98]	Peer-reviewed analysis[98]
• The Dutch Choices Program, a signposting program similar in concept to the Australian Tick Program, demonstrated that if all foods were reformulated to meet the specific nutrient criteria of the Program, then average population consumption in 19- to 30-year-old Dutch adults of saturated fat could reduce by 40%, trans fat by 63%, added sugars by 36% and sodium by 23% of current intake.[68,102,103] • The observed reduction in trans fatty acids in specific food products was modelled to calculate the average trans fatty acid intake and it was found that it significantly decreased by 0.2% E.[102]	Peer-reviewed analysis and data modelling[102] Data modelling[68,103]
• A coordinated approach in Denmark, involving mandatory labelling of trans fat and mandatory reformulation of trans fat in processed food was introduced in 2003. While average per person intakes had decreased from approximately 7.5 g in 1976 to below 1 g/day in 1996, the Danish Nutrition Council (DNC) importantly identified that particular subgroups may still be consuming up to 5 g trans fat per day. The DNC considered legislation along with industry engagement necessary to improve the health of these subgroups. As of 2005, population *and* individual intake of trans fat is negligible.[64]	Peer-reviewed article[64]
• A French study demonstrated that improving the nutritional profile of items from breakfast cereals, biscuits and pastries, and bread-based categories with the lowest nutritional quality would lead to significant improvements in the average consumption per person of added sugar (4–14% reduction), total fat (5–12% reduction), fibre (11–19% increase) and sodium (9–16% reduction).[80]	Data modelling[80]

Impact on cardiovascular health outcomes

Findings	Study type
• In Mauritius, where the commonly used cooking oil, palm oil, was substituted with soya bean oil, a survey demonstrated a corresponding and statistically significant 0.79–0.82 mmol/L drop in total cholesterol concentrations in the adult population between 1987 and 1992.[104] A limitation of this study was the absence of acknowledgement of major or residual confounders.	Cross-sectional survey[104]
• Finland introduced a voluntary sodium reduction program over 30 years, incorporating food reformulation, consumer education and warning labels on high salt foods. A reduction in population salt intake was observed in parallel with a 10 mmHg reduction in both diastolic and systolic blood pressure. A corresponding 60–80% reduction in stroke and cardiovascular disease mortality was observed during the same time period.[92,117,118,120,121] While concurrent primary prevention strategies were in place in Finland during this time, the fall in blood pressure has been attributed to the dramatic decrease in salt intake.[92]	Peer-reviewed article[92,117] Analysis of cross-sectional population surveys[118,120,121]
• A meta-analysis of 13 randomised controlled trials and four prospective cohort studies found that: o replacing partially hydrogenated vegetable oils (containing trans fat) with polyunsaturated (non-hydrogenated) fat can reduce the total cholesterol: high-density lipoprotein ratio by 0.67 for each 1% E replaced[116] o replacing 7.5% E from partially hydrogenated vegetable oils (containing trans fat) with polyunsaturated (non-hydrogenated) fat can reduce coronary heart disease risk by 16–40%.[116]	Meta-analysis and data modelling[116]
• In Australia, it is estimated that a mandatory reformulation program reducing the sodium content of all bread, margarine and cereal products in line with Heart Foundation Tick criteria would avert 18% of the burden of disease associated with excess dietary salt consumption.[37]	Data modelling[37]
• Reducing trans fat intake in the United States, through mandatory trans fat labelling and subsequent reformulation, would reduce the incidence of heart attack by 600–1,200 and save 200–500 lives per year.[95]	Peer-reviewed article[95]

Table 2: Cardiovascular health gains for the population

Sodium reduction in the population

Findings	Study type
• An estimated 610,000 Disability Life Adjusted Years (DALYs) could be averted if the Australian population reduced dietary sodium intake to 2,300 mg (6 g salt) per day.[37]	Data modelling[37]
• Reducing intake of sodium from processed food by 15–25% in Australia and New Zealand[62] would: o reduce the risk of a cardiovascular event by 10–20% o reduce risk of all-cause mortality by 6–14%. • Projected to 2018: o the number of heart attacks averted in Australia would be 5,800–9,700 and in New Zealand would be 1,600–2,700 o the number of strokes averted per annum in Australia would be 4,900–8,200 and in New Zealand would be 1,200–2,000 o reducing sodium intake from salt in processed foods by 15% would avert 20,786 DALYs from stroke and heart attack in Australia, and 6,078 DALYs in New Zealand o reducing sodium intake from salt in processed foods by 25% in Australia would avert 32,939 DALYs from stroke and heart attack, and 10,156 DALYs in New Zealand.	Data modelling[62]
• Reducing dietary intake of sodium in the United States (US) to the upper limit of 2,300 mg (6 g salt) has been estimated to reduce the prevalence of hypertension by 30% or 11 million new cases, save US$18 billion and save 312,000 Quality Adjusted Life Years (QALYs).[123] • A 1,200 mg (3 g salt) reduction from current intake can reduce incidence of coronary heart disease (CHD) by up to 120,000, stroke by up to 66,000, heart attack by up to 99,000 and reduce mortality by up to 92,000 per year.[77] • If population sodium consumption was only reduced by 400 mg (1 g salt), incidence of CHD would still be reduced by up to 40,000, up to 35,000 for heart attack, up to 23,000 for stroke, and up to 32,000 deaths from any cause could be averted.[77]	Data modelling[77,123]
• The prevalence of hypertension in Canadians is expected to decrease by 30%, resulting in an estimated annual healthcare saving of CAD$430 million if mean dietary sodium intake was decreased by 1,840 mg/day (5 g salt).[122]	Data modelling[122]
• Reducing population consumption by 1,200 mg (3 g salt) per day in the United Kingdom (UK) would reduce mean systolic blood pressure (SBP) by approximately 2.5 mmHg, annually preventing approximately 4,450 deaths from cardiovascular disease and saving £40 million.[76]	Data modelling[76]
• Reducing population consumption of sodium to 2,000 mg (5 g salt) per day in Norway would reduce the risk of stroke by 4.2%, the risk of myocardial infarction by 3.8% and the use of anti-hypertensives by 4.9%.[124] Over 25 years, this translates into a reduction in heart attack and stroke mortality by 7,000 and 4,500 respectively, and 87,000 life years saved.[124]	Data modelling[124]

Saturated fat reduction in the population

Findings	Study type
• Reducing saturated fat consumption from 13.3% of total energy intake to 12.8% in the UK population would deliver £200 million in healthcare cost savings and save 217,500 QALYs.[89]	Data modelling[89]
• Scenario modelling in Australia and New Zealand based on the potential benefits of nutrition and health-related claims on labelling demonstrated that if population intake of saturated fat could be reduced by 15 to 25% over 10 years, the projected gains in 2018 would be 9,811 to 16,409 DALYs averted in Australia and 2,689 to 4,429 DALYs in New Zealand in 2018.[62]	Data modelling[62]

Trans fat reduction in the population

Findings	Study type
• The near elimination of industrially produced trans fats in the US food supply may result in between 6 and 19% or 72,000 to 228,000 fewer cardiovascular disease events each year.[125]	Review[125]

Other

Findings	Study type
• Reducing 1 g added sugar per 100 g carbonated beverage has the potential to reduce body weight loss of 9.5 million kg per year globally.[67]	Data modelling[67]

Table 3: Cost-effectiveness of food reformulation initiatives

Cost-effectiveness of food reformulation initiatives	
Findings	**Study type**
• The health and economic benefits of population level campaigns to reduce dietary intake of sodium, saturated fat and trans fat is established.[5,8,10,11,37,61,63,76,77,79,92,96,117,122-124,126,127,149-152]	Systematic review[5,8] Randomised control trial[10] Peer-reviewed article[11,63,79,92,117,126] Peer-reviewed commentary[61,149,151] Data modelling[37,76,77,122-124,127,150,152] Non-peer reviewed report[96]
• Reformulation, as part of broader strategy to meet population level nutrient intake, is a cost-effective public health strategy to reduce cardiovascular disease risk.[37,71,76,77,122,124,126,127] • Ultimately, any costs associated with reformulation are outweighed by the health and economic benefits.[71] • A five-year investment of £15 million by the United Kingdom Food Standards Agency on a comprehensive salt reduction program (including reformulation) has been estimated to prevent 6,000 cardiovascular deaths per year and save approximately £300 million a year. These cost savings would be substantially greater if broader societal costs (such as improvements in work productivity) were considered.[76] • Reducing trans fat intake in the United States, through reformulation and mandatory trans fat labelling, would save US$1–2 billion in healthcare costs.[95]	Non-peer reviewed report[71] Peer-reviewed article review[95,126] Data modelling[37,76,77,122,124,127]

Table 4: Characteristics of an effective food reformulation program

A mandatory reformulation program is the most effective approach	
Findings	**Study type**
• Both voluntary and legislated approaches to reducing sodium, saturated fat and trans fat have demonstrated the potential for substantial health and economic benefits.[37,62,67,76,77,79,80,122-124,127,152]	Data/scenario modelling[37,62,76,77,80,122-124,127,152] Peer-reviewed analysis[79] Peer-reviewed article[67]
• A legislated approach to population dietary sodium is more cost-effective than a voluntary approach.[37,79,127]	Peer-review article[79] Data modelling[37,127]
• An Australian impact analysis indicated that mandatory reformulation, in the form of mandatory sodium criteria based on the Australian Heart Foundation's Tick criteria, was likely to be 20 times more effective than a voluntary incentive reformulation program in improving cardiovascular outcomes.[37]	Data modelling[37]
• A mandatory approach to sodium reformulation has been demonstrated to be twice as cost-effective and avert twice as much of the burden of disease compared to a voluntary approach.[127]	Data modelling[127]
• Legislation to reduce population sodium intake is supported[50,77,123] in consideration of the limitations to a voluntary approach; namely the concerns associated with industry self-regulation[153-155] and that a voluntary approach provides limited incentive to promote reformulation of all products beyond those eligible to carry a health claim or high-end products.[50]	Data modelling[77,123] Non-peer reviewed report[50] Peer-reviewed commentary[153-155]
• Regulation of reformulation creates a level playing field so as not to disadvantage progressive companies.[79]	Peer-reviewed article[79]
• The greatest population health gain can be achieved by coordinating a mandatory (sodium) reformulation program alongside a mass media consumer education campaign and individual risk factor treatment in high risk groups.[127]	Data modelling[127]
• The United Kingdom Food Standards Agency and Food Standards Australia and New Zealand support voluntary trans fat reduction, claiming the effectiveness of the current non-regulatory approach to date in reducing trans fat intake.[29,156]	Non-peer reviewed report[29,156]
• The priority in commencing a mandatory reformulation program is targeting the foods that contribute the most to population intake of selected nutrients.[70,101,132] This should be a consideration in any food reformulation initiative.[70,101,132]	Peer-reviewed article[70] Non-peer reviewed report[101,132]

Incremental change is likely to be the most effective

Findings	Study type
• Consumer acceptance of reformulated products is crucial.[71,105,131,135,138] • A program that considers thoroughly all elements of consumer acceptance at each progressive level of the program is required.[70-72,90,131,132,138]	Non-peer reviewed commentary[131] Non-peer reviewed report[71,90,105,132,135,138] Peer-reviewed article[70,72]
• In 60 participants, paired tests revealed no statistically significant difference was found for a 20% reduction of sodium in bread.[157] • In 110 volunteers, a gradual 5% reduction of sodium content in bread per week over six consecutive weeks did not affect consumer acceptance.[146] • A small study demonstrated that the preferred level of salt in food is dependent on the level of salt consumed in the diet, and that this preferred level can be lowered after a reduction in salt intake.[145] This was supported by a study that also demonstrated that participants adapt to the taste of foods containing less salt following the restriction of sodium intake.[144]	Randomised controlled trial[144,146,157] Non-randomised controlled trial[145]
• Small, progressive reductions of sodium in reformulated foods is supported[71,132,142,143] and may be applicable for reduction/addition of other nutrients.[142]	Non-peer reviewed article[142] Non-peer reviewed report[71,132] Peer-reviewed article[143]

Reformulation must be category-specific and adopt a multi-nutrient approach to be feasible and cost-effective

Findings	Study type
• Consideration is required for each product or product category as taste, texture, structure, microbial safety and nutrient replacement will vary dependent of the food product.[65,66,71,84,90,99,101,105,129-134,136-140,158]	Peer-reviewed article[65,84,99,129,133,134,136,137,139,140,158] Peer-reviewed commentary[66] Non-peer reviewed commentary[90,131] Non-peer reviewed report[71,101,105,130,132,138]
• Unavoidable costs associated with reformulation[70,71,88,89,107,108,135,136,141] can be minimised if the product composition as a whole is considered (multi-nutrient) instead of specific nutrients at different times.	Peer-reviewed article[70,107,108,136,141] Non-peer reviewed report[71,88,89,135]

Reformulation should be part of an approach that includes front-of-pack labelling and consumer awareness

Findings	Study type
• Government regulation, including consumer awareness campaigns and nutrient labelling, drives reformulation.[71,105,147]	Non-peer reviewed report[71,105] Peer-reviewed article[147]
• Awareness of the relationship between particular nutrients and health was reported to increase by several initiatives running consumer awareness campaigns.[64,72,74,85] • Such consumer awareness campaigns have the potential to increase consumer demand for healthier products.[105] • In the case of saturated and trans fat, communicating reformulation initiatives after commencement of consumer awareness programs linking those nutrients to health may be a strategic approach – informed consumers will likely seek foods lower in saturated and trans fat after such campaigns.[89,138]	Peer-reviewed article[64,72,74] Non-peer reviewed report[85,89,105,138]
• The nutrient criteria of interpretive front-of-pack labelling and mandatory nutrient labelling has encouraged reformulation in Australia,[106] Canada,[99] Finland,[159] New Zealand,[109] the Netherlands,[68] Sweden,[70] the United States,[95,147] and the United Kingdom.[71,105]	Peer-reviewed article[70,79,95,99,106,109,147,159] Data modelling[68] Non-peer reviewed report[71,105]

Government-led and comprehensive stakeholder engagement

Findings	Study type
• Key characteristics for successful reformulation programs, namely sodium initiatives, include strong leadership, regular monitoring (clear and consistent mechanisms), extensive stakeholder engagement in the development/ implementation and mass media campaigns.[72,85]	Review[72] Non-peer reviewed report[85]
• The food system must be considered in developing an effective reformulation program. Successful reformulation depends on the adaptability of the production processes all the way down the supply chain including the cultivation, harvest and supply of raw ingredients.[101,107,108,136,141,147]	Peer-reviewed article[107,108,136,141,147] Non-peer reviewed report[101]
• Government leadership, with dedicated staff and resources, is essential in leading a reformulation program which consults and involves stakeholders in the planning, implementation and assessment of the strategy.[71,72,85] • Additionally, the complexity involved in reformulation programs requires all sectors (government, industry, public health, academics and media) to work collaboratively to meet reformulation goals.[64,85,107]	Non-peer reviewed report[71,85] Peer-reviewed article[64,72,107]

Commitment must be made to monitoring and evaluation

Findings	Study type
• Clear and consistent mechanisms for monitoring of reformulation initiatives is essential to demonstrate progress.[71,72,80]	Non-peer reviewed report[71] Peer-reviewed article[72,80]
• Detailed data on the nutritional characteristics of food items and individual consumption patterns (population intake) is needed to analyse the impact of changes to the food supply on public health. The lack of this information and the call for better monitoring is a consistent theme in the literature.[80,105,148]	Non-peer reviewed report[105] Peer-reviewed article[80,148]

Evidence gaps and limitations

This rapid review has identified several research gaps. A limited number of food reformulation programs have evaluated their impacts on population health outcomes. As discussed, this is likely due to the complexity of evaluating initiatives embedded in a broader public health strategy, as reformulation often is. Adding to this is the complex interplay between the environment, individual behaviours and chronic disease. Regardless, the identification of a small number of studies demonstrating impact on population dietary intake and health outcomes indicates that evaluation is possible with consistent, comprehensive and long-term monitoring strategies.

Much of the evidence draws on the potential benefits of population level interventions through modelling and these studies have demonstrated the considerable health gains possible. While there are some inherent limitations in modelling studies (such as assumptions about distribution of disease across population subgroups, and projecting disease trends based on current data), these generally result in conservative estimates being projected. Consequently, the potential benefits are likely to be much greater than those described.

Most of the studies in the reformulation literature focused on sodium. Few studies modelled the potential benefits of reducing saturated fat and trans fat. No studies explored reformulation of energy, fruit and vegetables, fibre and wholegrains.

While there is some data describing the impact of the Heart Foundation Tick Program on the food supply, there is now an opportunity to examine the program's longer term impacts and health outcomes.

Future research

The Heart Foundation recommends future research in the following areas.

In the short term:

Data and scenario modelling of the population dietary, health and economic impacts of reformulating nutrients (beyond sodium) in commonly consumed processed foods in Australia.

Investigation is required into the challenges, opportunities and health and economic benefits achievable as a result of reformulating nutrients beyond sodium (saturated fat, trans fat, total energy, wholegrains, fruit and vegetables and fibre) in commonly consumed processed foods. There is also scope for analyses of the Australian food industry's costs associated with single versus multi-nutrient reformulation. Additional research in these areas would assist in guiding the agenda for Australia's food reformulation strategy towards a category-specific, multi-nutrient approach.

Modelling the health and economic impacts of specific changes to the food supply achieved by reformulation incentive programs.

The literature has demonstrated a gap in linking the changes that a reformulation incentive program makes in the food supply and modelling the changes in population intake and/or health outcomes. The Dutch Choices Program is a good example of the modelling that can be done for a signposting program. The Heart Foundation recognises the opportunity in translating the significant food supply gains that have been made by the Tick Program to the impact on the Australian population.

In the long term:

A comprehensive evaluation of Australia's food reformulation strategy.

Measuring the effectiveness of Australia's food reformulation strategy will require access to complete data sets of nutrient composition, population dietary intake and sales trends. In addition, the measurement of health outcomes occurring over the same time period is essential to monitor and evaluate the effectiveness of a food reformulation program. Regardless of the implementation of a mandatory or voluntary approach to reformulation, ongoing commitment to monitoring and evaluation is needed.

Recommendations

Reformulation should form part of a comprehensive and coordinated approach to improving population nutrition. The Heart Foundation is calling on the Australian Government to:

- Enforce mandatory category-specific nutrient targets for processed foods. Such regulation should involve progressive and incremental change. It should also apply to imported foods. Until such time, the Food and Health Dialogue should continue to work collaboratively with industry. Greater emphasis should be placed on setting multi-nutrient targets where possible. This would minimise industry costs associated with reformulation. In addition, manufacturers should be encouraged to reformulate products likely to have the greatest impact on population health (i.e. those with the highest sales volume).
- Be a global leader in developing a comprehensive monitoring and evaluation system. Australia has the opportunity to make a substantial contribution to the evidence base by measuring the short- and long-term impacts of a national food reformulation program. Such a program should include:
  - ongoing commitment to comprehensive measurement of dietary intake (including biomarkers) through the Australian Health Survey every five years across all population subgroups
  - a 24-hour urinary sodium excretion collection in the Australian Health Survey's biomedical component, to benchmark and track population salt consumption
  - funding for the development of a database that relies on the independent and standardised collection of Nutrition Information Panel data and sales data.
- Work with industry and public health stakeholders to develop a robust, interpretive mandatory front-of-pack (FOP) labelling system that genuinely guides consumers to a healthier choice and encourages reformulation. An effective FOP labelling system has been shown to provide added incentive for food manufacturers to improve their products' nutritional profiles and drive consumer demand for healthier products.
- Fund an adjunct social marketing (consumer education) campaign to increase consumer demand for healthy food and shift social norms about reasonable levels of risk-associated nutrients in food. The Dialogue was created with the intention of including public education as a key component of the reformulation initiative. The Australian National Preventive Health Agency could be engaged to work with the Dialogue on this social marketing campaign.

The Heart Foundation is calling for industry to:

- Apply the Dialogue's nutrient targets to all their products within a category to achieve maximum health benefit. At a minimum, targets should be applied to their largest selling food items.
- Reformulate existing products in addition to formulating new products. Formulating new products without improving existing products is unlikely to bring about the desired population outcomes.

The Heart Foundation will continue to work with each of the key stakeholders in building a healthier food supply. Specifically, the Heart Foundation will:

- Continue to contribute to the evidence base on reformulation efforts. This includes development of a robust long-term evaluation strategy for the Tick Program to measure population health impacts as a result of food supply change.
- Provide expert analysis on food category data and informed opinion on the development of meaningful and realistic targets.
- Provide a platform for supporting health professionals and empowering consumers through effective consumer messaging and community mobilisation tools.

Glossary

Food reformulation	Changing the nutrient content of a processed food product to either reduce the content of negative nutrients such as sodium, saturated fat, trans fat or energy (kilojoules) or to increase the content of beneficial nutrients such as dietary fibre, wholegrains, fruit, vegetables and unsaturated fats.
Processed foods	The food products resulting from the application of physical, chemical or biological processes, or combinations of these, to a primary food commodity, and intended for sale to the consumer or for use as an ingredient in the manufacture of a food product or for further processing.[160] Most foods are processed in some way. Many foods found in nature are inedible, unpalatable or perishable if not subjected to food processing such as cooking or preserving.[44] Some foods are minimally processed. Others are ultra-processed.[44]
Ultra-processed foods	Ultra-processed products are characteristically formulated from 'refined' and 'purified' ingredients extracted from their original raw materials. While they may imitate their original constituents, they rarely contain original food components, and are often energy dense, nutrient poor. Examples include (but aren't limited to) biscuits, bread, cakes and pastries; ice-cream; chocolates, confectionery, cereal bars, chips and crisps; sauces; cheeses; processed meat, hot dogs, sausages and burgers.[44]
Energy	Energy is not a nutrient itself but is released from carbohydrates, proteins, fats and, to a lesser degree, alcohol. It is measured in kilojoules or calories. 1 calorie = 4.185 kJ[22]
Sodium	A component of the molecule sodium chloride, also known as (table) salt. 1 g table salt = 400 mg sodium[22]
Saturated fat	A type of fat that is found in animal foods, hardened liquid vegetable oils, palm oil and coconut oil.[22]
Trans fat	A type of fat with specific hydrogen bonds that is found naturally in cows' milk and beef, but can also be produced industrially through hydrogenation processes to harden liquid fats.[22]
Nutrition Information Panel	Mandatory panel on all food packages containing nutrition information as specified by Food Standards Australia and New Zealand.[160]

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