



Review of the Food Standards Australia New Zealand Act 1991

Scoping paper for public consultation

2 October 2020

Contents

Executive summary.....	2
1 Background and context to the Review.....	8
1.1 There is a clear, ongoing need for regulation of food.....	9
1.2 The food regulatory system can be improved, but it is not broken.....	9
1.3 The Act is almost 30 years old and has not kept up with changes in practice.....	10
1.4 Five focus areas have been identified for this Review.....	11
2 Objectives.....	12
2.1 Regulatory and non-regulatory objectives for the food system need to be clarified.....	13
2.2 Legislative changes may clarify the Act's objectives.....	16
3 Functions.....	19
3.1 FSANZ's statutory functions could be clarified.....	19
3.2 Statutory functions could be amended to reflect FSANZ's agreed scope of practice.....	21
4 Legislative processes and decision-making arrangements.....	24
4.1 There are currently limited mechanisms for holistic reviews of standards to ensure they remain suitable and fit-for-purpose.....	25
4.2 A strategic approach to reviewing standards could better future-proof the regulatory framework.....	26
4.3 Prescriptive statutory processes to amend food regulatory measures do not enable a risk-based or flexible response.....	27
4.4 Legislative changes could support more risk-based processes and decision-making.....	29
4.5 Additional pathways to develop or vary food standards could be beneficial.....	31
4.6 New pathways to amend food standards may support a more timely and responsive regulatory system.....	34
5 Partnerships.....	37
5.1 Governments' and FSANZ's priorities are not always aligned.....	37
5.2 Legislative and operational reforms could improve alignment of policy development and standard-setting.....	38
5.3 Inconsistent interpretation and enforcement of food standards is an enduring issue for the system.....	39
5.4 Legislative and operational changes may improve the implementation and enforcement of food standards.....	40
5.5 The boundaries between food and medicine – and their respective regulatory frameworks – are not always clear.....	43
5.6 Three reform ideas have been identified to address issues at the food medicine interface.....	46
6 Operations.....	49
6.1 FSANZ's governance is enshrined in legislation.....	49
6.2 Legislative change could support more efficient and effective governance for FSANZ.....	50
6.3 FSANZ has multiple priorities and constrained resources.....	51
6.4 There are opportunities for legislative and operational reform to ensure adequate resourcing for FSANZ.....	53
7 Key reflections.....	55
8 Next steps.....	56
Appendix A Review Terms of Reference.....	57
Appendix B FSANZ Act Review Steering Committee members.....	59

Executive summary

The *Food Standards Australia New Zealand Act 1991* (the Act) is one of several foundational instruments that make up the joint food regulatory system. By empowering Food Standards Australia New Zealand (FSANZ) to set and amend food standards and undertake other core functions, the Act underpins the safety of our food supply and provides a regulatory framework for how foods can enter the market in Australia and New Zealand.

The Act is now undergoing its first major review in almost 30 years (the Review), which presents an exciting opportunity for modernisation. The Terms of Reference (ToR) are at Appendix A.

The Australian Government Department of Health (Department of Health) is leading the Review in partnership New Zealand Ministry for Primary Industries (MPI) and has contracted Nous Group (Nous) to undertake the initial phase of this work. This work is guided by the FSANZ Act Review Steering Committee (members at Appendix B).

In line with a comprehensive regulatory review, there is an impetus to explore the rationale for food regulation and the role of FSANZ as a standard-setting body. Research and stakeholder engagement to date has illustrated the case for regulation; regulation protects a public good and addresses market failures. Feedback from government, industry, consumer and public health stakeholders has been unanimous in its support for the high standards Australia and New Zealand require of food products and has recognised the critical role of government oversight.

Many stakeholders have been quick to stipulate that the Australia-New Zealand food regulatory system can be improved, but it is not broken; and FSANZ delivers a highly valued service to the community. The bi-national nature of the regulatory scheme has also been highlighted as one of the key strengths of the system and is often held up as a good example of Closer Economic Relations between the two countries.

With the ongoing need for food regulation and for FSANZ well established, there is now an opportunity to consider how the provisions within the Act can support best-practice regulation and standards-setting.

The ToR call for the Review to examine the Act and FSANZ's operations, with several key areas being called out for specific consideration. At this time, there is an opportunity to consider how legislative and operational changes can assist FSANZ to efficiently and effectively deliver its current statutory functions, and also consider whether FSANZ should be taking on a wider role, either in Australia and/or New Zealand.

The Review has been running since July 2020 and this scoping paper builds on research and consultation completed to date. It summarises the issues and tensions observed within the system and articulates possible ideas for reform. It is deliberately solutions-focused and designed to elicit commentary on what impact various regulatory changes might have for different stakeholder groups, as well as encourage new ideas for consideration. Importantly, it does not assume a position on which of the reform ideas are the right ones to pursue.

Feedback gathered in response to the scoping paper will inform a shortlist of reform opportunities that will be further researched and subject to a cost-benefit analysis. A summary of stakeholder views on the scoping paper will be provided as part of further regulatory impact analysis work.

Findings will ultimately be collated into a Regulatory Impact Statement and further consultation will be led by the Department of Health in collaboration with its New Zealand counterpart ahead of any legislative changes.

The issues and reform ideas that are discussed in this scoping paper are summarised at Table 1. The reform ideas are not intended to be mutually exclusive and could be considered separately or in conjunction with one another.

Specific discussion questions have been posed throughout this paper. Feedback will be collected until midday AEST 16 November 2020 via *the Australian Department of Health Consultation Hub*.

Government departments, businesses, consumer groups, peak bodies, individuals and all other stakeholders are invited to make submissions.

Table 1 | Overview of key issues and possible reform ideas

Section	Focus area	Key issues	Possible reform ideas
2	Objectives	<p>Regulatory objectives for the food system need to be clarified</p> <p><i>It is not clear what is covered by the term 'public health protection'</i></p> <p><i>The intent of 'enabling consumers to make informed choices' has evolved over time</i></p> <p><i>FSANZ must have regard to the desirability of an efficient and internationally competitive food industry, but this is not an explicitly stated goal for FSANZ in s 3 of the Act</i></p> <p><i>There are structural tensions within FSANZ's objectives when developing food regulatory measures.</i></p>	<p>Reform idea 1 - Define 'public health' and 'safety' in legislation to affirm the inclusion of long-term health and nutrition as a core objective</p> <p>Reform idea 2 - Recognise trade as a core goal and reframe consumer choice as a factor to which FSANZ 'must have regard'</p> <p>Reform idea 3 – Establish criteria in the Act that the Forum must meet to request a review of a draft regulatory measure</p>
3	Functions	<p>FSANZ's statutory functions could be clarified</p> <p><i>FSANZ has a broad range of statutory functions</i></p> <p><i>Statutory functions could be amended to reflect FSANZ's agreed scope of practice</i></p> <p><i>FSANZ's role could be better defined in some cases</i></p> <p><i>FSANZ could potentially undertake broader roles or functions to deliver greater value to the system, if appropriately resourced.</i></p>	<p>Reform idea 4 - Amend the Act to better reflect the functions FSANZ currently delivers, particularly as they relate to supporting long-term health and nutrition</p> <p>Reform idea 5 – Amend s 13 of the Act to reflect a broader range of functions that FSANZ could deliver now and in the future. This could include new functions relating to:</p> <ul style="list-style-type: none"> • providing a central hub of information relating to food safety • coordinating food safety research • combatting food crime and food fraud • undertaking public education campaigns to support broader health and nutrition
4	Legislated processes and	<p>There are currently limited mechanisms for holistic reviews of standards to ensure they remain suitable</p>	<p>Reform idea 6 – Remove exemption of food standards from sunseting arrangements</p>

Section	Focus area	Key issues	Possible reform ideas
	decision-making	<p>and fit-for-purpose</p> <p><i>Food standards are exempt from sunset provisions</i></p> <p><i>The current approach to reviewing standards is reactive</i></p> <p><i>There are currently limited mechanisms for holistic reviews of standards to ensure they remain suitable and fit-for-purpose.</i></p>	<p>Reform idea 7 – Resource FSANZ to undertake regular, more holistic reviews of food standards</p>
		<p>Prescriptive statutory processes to amend food regulatory measures do not enable a risk-based or flexible response</p> <p><i>The full suite of regulatory measures is not being leveraged</i></p> <p><i>Decision-making arrangements for regulatory measures are unusual.</i></p>	<p>Reform idea 8 – Reframe legislation to support more agile, risk-based processes. This might include:</p> <ul style="list-style-type: none"> transferring much of the detail from the Act into the FSANZ Regulations establishing a policy framework to guide how to best use the hierarchy of legislative instruments available to FSANZ redefining processes to develop or vary regulatory measures based on risk <p>Reform idea 9 – Redefine the decision-making arrangements to support timelier and more efficient sign-off of regulatory measures</p> <ul style="list-style-type: none"> Providing for both the Forum and the FSANZ Board to delegate decision-making about food standards Providing for the Forum to delegate decision-making to FSANZ for more technical amendments
		<p>Additional pathways to develop or vary food standards could be beneficial</p> <p><i>Current statutory processes provide limited ability to use international standards and risk assessments</i></p> <p><i>An enhanced role for industry through self-assessments would require appropriate regulatory oversight and</i></p>	<p>Reform idea 10 – Provide for FSANZ to adopt or accept risk assessments from overseas jurisdictions</p> <p>Reform idea 11 – Enable FSANZ to adopt international standards. This could include:</p> <ul style="list-style-type: none"> unilateral adoptions, such as adoption of new standards to Codex

Section	Focus area	Key issues	Possible reform ideas
		<i>safeguards.</i>	<ul style="list-style-type: none"> mutual recognition of standards with select other international jurisdictions <p>Reform idea 12 – Create industry-led pathways to expedite applications and bring new products to market</p>
5	Partnerships	<p>Governments' and FSANZ's priorities are not always aligned</p> <p><i>FSANZ and the Forum do not always have a shared vision of priorities.</i></p>	<p>Reform idea 13 – Facilitate joint agenda setting between FSANZ and the Forum</p> <p>Reform idea 14 – Amend statutory timeframes to support more strategic prioritisation of work</p>
		Inconsistent interpretation and enforcement of food standards is an enduring issue for the system	<p>Reform idea 15 – Enhance FSANZ's role in providing guidance about food standards within its current statutory remit. This could include:</p> <ul style="list-style-type: none"> including a statement of intent alongside food standards in the Food Standards Code resourcing FSANZ to update and maintain industry guidelines <p>Reform idea 16 – Provide for FSANZ to give binding interpretive advice on food standards. This could include:</p> <ul style="list-style-type: none"> introducing compliance codes or advice introducing a power for FSANZ to make binding interpretations about food standards <p>Reform idea 17 – Enhance FSANZ's regulatory role by providing limited enforcement powers This could include:</p> <ul style="list-style-type: none"> providing FSANZ the statutory remit and powers to regulate specific food

Section	Focus area	Key issues	Possible reform ideas
			standards, such as novel foods or health claims
			<ul style="list-style-type: none"> providing FSANZ with the statutory remit and powers to regulate food that is sold across state or territory borders in Australia or exported from Australia or New Zealand.
		<p>The boundaries between food and medicine – and their respective regulatory frameworks – are not always clear</p> <p><i>The food-medicine interface is an enduring issue</i></p> <p><i>Clear delineation of food and medicine defies a simple solution</i></p> <p><i>Limited oversight of food-health claims may contribute to the food regulatory system being seen as a 'path of least resistance'.</i></p>	<p>Reform idea 18 – Focus efforts on improving the food-medicine interface through regulatory practice</p> <p>Reform idea 19 – Broaden the role of FSANZ to assess general level health claims</p> <p>Reform idea 20 – Align definitions and powers in legislation between therapeutic goods and foods</p>
6	Operations	<p>FSANZ's governance is enshrined in legislation</p> <p><i>Statutory requirements around Board composition, nomination and appointment processes could be improved</i></p>	<p>Reform idea 21 – Streamline Board appointments and nominations</p> <p>Reform idea 22 – Establish minimum term length for Board members</p> <p>Reform idea 23 – Reduce Board size.</p>
		<p>FSANZ has multiple priorities and constrained resources</p> <p><i>Funding constraints underpin FSANZ's resourcing model</i></p> <p><i>Cost recovery mechanisms can be considered as part of the Review</i></p>	<p>Reform idea 24 – Expand scope of applications for which FSANZ can recover costs</p> <p>Reform idea 25 – Provide for limited expansion of scope of activities for which FSANZ can recover costs.</p>

1 Background and context to the Review

The Australian and New Zealand food system is made up of a complex mix of regulatory and policy schemes which safeguard the food we eat.

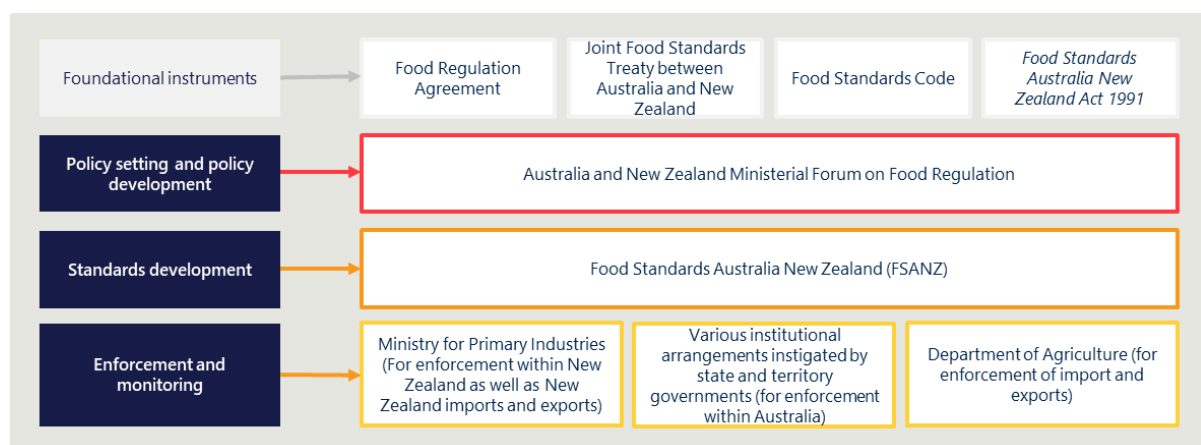
In November 2019, the Australia and New Zealand Ministerial Forum on Food Regulation (the Forum) agreed an ambitious plan to reform the regulatory system to ensure it remains strong, robust and agile into the future. The Review is a critical part of this plan and considers how the *Food Standards Australia New Zealand Act 1991* (the Act) and FSANZ's associated operations can be reformed to support best practice regulation and standards setting.

As shown in Figure 1, the Act sits within a complex environment that makes up the food regulatory system. Of particular note:

- **FSANZ is the body that develops or varies food regulatory measures (among other functions) and its authority is derived from the Act.** While FSANZ is independent in its decision-making about food regulatory measures, it works closely with the Forum to progress key objectives for the food system.
- **The Forum is the body that sets the policy direction for the joint food system.** It is comprised of ministers from all Australian and New Zealand jurisdictions. The Forum is not established by the Act, but by the Food Regulation Agreement (FRA). A separate review of the FRA is underway and includes setting a vision for the system as well as mechanisms to better align regulatory enforcement approaches between Australian states and territories. Public consultation on this Review will occur in the near future and feedback from the consultation for both reviews will inform each other.
- **Enforcement of food standards is carried out by jurisdictions.** In Australia, this includes a mix of state and local governments; statutory regulators and private auditors, as well as the Department of Agriculture, Water and the Environment for imported foods. In New Zealand, this is conducted by MPI.

The scope of the Review is confined to the Act and FSANZ's operations.

Figure 1 | Overview of the food regulatory system¹



¹ This figure is adapted from a figure on page 15 of the 2018 Food Export Review: *Underpinning trust, preparing for the future*.

1.1 There is a clear, ongoing need for regulation of food

The Australian Government is committed to a deregulation agenda that requires regulatory or legislative changes to be subject to a regulatory impact assessment which confirms that regulation is the most appropriate approach to addressing a policy problem.² Similarly, New Zealand is committed to modernisation of key regulatory systems to support innovation, increase efficiency and remove complexity while managing risk.³

Regulation is appropriate for example, if there is a market failure that must be corrected, or a public good to be protected and where voluntary action is insufficient to achieve these outcomes. Food is an area where the ongoing need for regulation is evident.

A safe food supply is a broad social good with considerable social, economic and strategic benefits. While food producers and manufacturers have a vested interest in assuring food is safe to eat, there is a clear ongoing role for government in the regulation of food that is broadly recognised and supported by stakeholders. This is for a range of reasons, including:

- Food supply chains are highly complex and increasingly integrated. This creates the potential for wide-reaching, harmful spill-over effects if the food supply is compromised or contaminated - both for consumers of food and businesses selling food products. These spill-over effects, and the significant associated risks, may not be adequately insured against by individual actors in the market.
- Conversely, sustained provision of a safe food supply has positive spill-over effects for society and industry, for example for export businesses that can leverage the strong reputation that food from Australia and New Zealand has in regional and global markets. This competitive advantage is a collective good that depends on central government oversight.
- Food consumption patterns are an important driver of individual wellbeing and broader public and population health. Government regulation of food can take a longer-term perspective of health and wellbeing and consider how regulation of food can promote broader social objectives, such as reduction in non-communicable food-related illnesses.
- Developing or varying food standards requires deep and broad technical expertise which is currently consolidated in FSANZ.

The role for government in regulating food is well established and supported. Given this, the Review's focus is on opportunities to improve food regulation through legislative changes to the Act and associated operations and responsibilities of FSANZ.

1.2 The food regulatory system can be improved, but it is not broken

The bi-national food regulatory system effectively safeguards the food supply in Australia and New Zealand and provides a common market and regulatory framework for both countries. Successive reviews of different aspects of the system have found that it generally functions well⁴ and that it is not

² Department of the Prime Minister and Cabinet (2020) *The Australian Guide to Regulatory Impact Analysis*. Commonwealth of Australia.

³ Fit for a Better World – Accelerating our Economic Potential (2020, available at:

<<https://www.mpi.govt.nz/dmsdocument/41031/direct>>

⁴ For example, a 2005 Review of the FRA found that the Agreement has made a positive contribution to the development of a national approach to food regulation within Australia, including through its co-operative structure, improved communications between portfolios and clearer administrative arrangements. A 2006 review of the Food Treaty found that most stakeholders consider that the Treaty has been successful in reducing barriers to trade. A 2018 Food Export Review found that “the Australian food system is

fundamentally broken - though there are opportunities for improvement, particularly in relation to responsiveness, flexibility and timeliness.

Stakeholders consulted to date for this Review note the value of FSANZ and the food regulatory measures it sets in ensuring food safety, supporting public health, and creating a strong reputation for Australian and New Zealand food that provides a competitive advantage.

1.2.1 The bi-national nature of the food system is a key strength

The bi-national character of the food regulatory system is recognised as a key strength by Australian and New Zealand stakeholders that delivers mutual economic and social benefits, through common food standards, joint policy development and a single food market.

The bi-national system provides expanded commercial opportunities for both Australian and New Zealand food businesses (enabled by the Trans-Tasman Mutual Recognition Arrangement) that facilitates substantial trade between the countries.⁵

FSANZ's bi-national role is highly regarded, in addition to its Australia and New Zealand-specific roles.

1.2.2 FSANZ is valued as a credible, independent and science-based body

FSANZ plays a vital role in instilling this confidence in developing food standards. This is grounded in its role as an independent standard-setting body that applies a rigorous scientific and risk-based approach to its role and functions. The significant technical expertise that FSANZ brings is cited by many stakeholders as a core strength of the system that should be preserved.

1.3 The Act is almost 30 years old and has not kept up with changes in practice

Since its establishment in 1991, the Act has been amended many times, however key parts of the Act have not undergone significant reform or review since that time.

Yet, in the intervening almost-30 years, there have been significant changes in consumer preferences, patterns and expectations in relation to food, as well as evolving government priorities and industry practices in the production and sale of food products. An increasingly integrated and global food market has been driving rapid changes in food supply, including the introduction of new and novel foods, and new challenges around maintaining food security.

At the same time, non-communicable food-related diseases like obesity continue to rise and governments are looking for new ways to support healthy eating habits at a population level. Further, consumers increasingly expect information to support a wide range of food preferences, including to make healthy choices about food.

This Review, therefore, considers some of the current challenges relating to food and the role of the Act and FSANZ in dealing with them. Specifically, it considers how legislative changes might support FSANZ to

performing reasonably well" and "has to date been reasonably well-functioning and have provided a competitive advantage to Australia's food exports."

⁵ For example, New Zealand's top two exports to Australia in the last five years have been *milk powder, butter, and cheese* and *preparations of milk, cereals, flour and starch*. Together, these contributed \$1.5bn to New Zealand's gross domestic product in 2019.

deliver its current statutory remit more efficiently and effectively, while also considering other roles FSANZ might play to support the food system in Australia and/or New Zealand.

1.4 Five focus areas have been identified for this Review

This paper presents issues and opportunities in terms of five key focus areas that have been identified and iterated through stakeholder consultation. These are shown in Figure 2 and discussed in turn.

Figure 2 | The focus areas explored in this scoping paper

KEY ISSUE CATEGORY		FOCUS IN SCOPING PAPER
	OBJECTIVES	Section 2 – The objectives of the Act and FSANZ’s objectives in developing or reviewing food regulatory measures.
	FUNCTIONS	Section 3 – FSANZ’s current statutory functions and the potential for FSANZ to undertake additional roles in Australia, New Zealand or both.
	LEGISLATIVE PROCESSES & DECISION MAKING	Section 4 – Statutory application and proposal processes and decision-making arrangements for changes to food standards.
	PARTNERSHIPS	Section 5 – FSANZ’s relationships within and outside the food regulatory system, including policy development, enforcement and the food-medicine interface.
	OPERATIONS	Section 6 – FSANZ’s governance, resource allocation and funding, including scope for cost recovery.

Discussion question:

1. Is there still a compelling case for regulating food? What market failure(s) should governments seek to address through regulation of food?
2. Are there other significant focus areas that should be considered as part of the Review?

2 Objectives

Articulating clear objectives in legislation is critical to effective regulation as it provides a clear direction about the outcomes sought by government intervention.

Food is currently captured under a number of different regulatory schemes (such as food regulation, consumer protection and biosecurity schemes), policies (such as health promotion activities led by departments of health) and agreements (including trade agreements such as those between Australia, New Zealand and other countries).

The Act works alongside the Food Regulation Agreement and the Joint Food Standards Treaty between Australia and New Zealand to enable the food regulatory system, but these documents all adopt slightly different wording around the objectives of food regulation.

In 2016, the Overarching Strategic Statement for the Food Regulatory System (OSS)⁶ was published to provide consolidated advice on the objectives of the system. This statement called out the following aims:

- protect the health and safety of consumers by reducing risks related to food
- enable consumers to make informed choices about food by ensuring that they have sufficient information and by preventing them from being misled
- support public health objectives by promoting healthy food choices, maintaining and enhancing the nutritional qualities of food and responding to specific public health issues
- enable the existence of a strong, sustainable food industry to assist in achieving a diverse, affordable food supply and also for the general economic benefit of Australia and New Zealand.

The OSS clarifies that in pursuing these aims, the overriding priority will always be protecting public health and safety.

Reflecting on the objectives of the Act is therefore an opportunity to consider the circumstances in which:

- the food regulatory system is the *right regulatory system* to pursue certain goals
- food standards and other regulatory measures are the *most appropriate legislative instruments* to pursue a certain aim or goal (compared to non-regulatory pathways)
- how well the functions FSANZ currently delivers – or could deliver – align with the *statutory objectives*.

The current wording of the Object of the Act is captured in section (s) 3 (shown in Table 2).

Table 2 | The Object of the Act

S 3 | Object of the Act

The Object of this Act is to ensure a high standard of public health protection throughout Australia and New Zealand by means of the establishment and operation of a joint body to be known as Food Standards Australia New Zealand to achieve the following goals:

- a) a high degree of consumer confidence in the quality and safety of food produced, processed, sold or exported from Australia and New Zealand
- b) an effective, transparent and accountable regulatory framework within which the food industry can work

⁶ Source: Ministerial Forum for Food Regulation. Overarching strategic statement for the food regulatory system. <https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/foodsecretariat-strategic-statement>

efficiently

- c) the provision of adequate information relating to food to enable consumers to make informed choices
- d) the establishment of common rules for both countries and the promotion of consistency between domestic and international food regulatory measures without reducing the safeguards applying to public health and consumer protection.

2.1 Regulatory objectives for the food system need to be clarified

Several issues have been identified around how the objectives of the Act are articulated.

2.1.1 It is not clear what is covered by the term 'public health protection'

The primary object of the Act in s 3 is to ensure a high standard of public health protection throughout Australia and New Zealand by means of the establishment and operation of FSANZ.

Many stakeholders to date have observed a lack of clarity around what 'protecting public health' (s 3) – as well as 'the protection of public health and safety' (s 18) – means. Specifically, it has been noted that they could refer to:

- preventing foodborne illness or injury, primarily in the acute, post-consumption period
- long term health, including through the prevention of obesity-related chronic disease.

The regulatory system was originally set up to assure food safety. For example, ensuring that food was manufactured in hygienic spaces and used safe ingredients was important for preventing injury or illness. Increasingly, however, the regulatory system has been used as a platform to pursue non-food safety matters, such as to encourage healthier eating and prevent food-related chronic disease. Preventable chronic disease related to diet present significant issues for Australia and New Zealand, in terms of premature deaths⁷, reduced quality of life⁸ and economic costs.⁹

Clarifying the terms 'public health' and 'safety' has important implications:

- a narrower definition focused on food safety primarily in the acute post-consumption period means that the food should only be regulated by FSANZ to prevent injury or illness; longer-term public health and nutrition objectives should only be pursued through other channels
- a broader definition encompassing both acute and long-term health provides a legislated basis for work that is already being carried out through the regulatory system. The Review therefore becomes about ensuring that FSANZ's functions and the provisions it must follow in the Act are appropriate to achieving this dual focus.

⁷ Ministry of Health 2020, 'Global Burden of Disease Study provides important insights into the health of New Zealanders', available at: <<https://www.health.govt.nz/news-media/news-items/global-burden-disease-study-provides-important-insights-health-new-zealanders>>

⁸ Australian Institute of Health and Welfare 2010 'Premature mortality from chronic disease', available at: <<https://www.aihw.gov.au/reports/chronic-disease/premature-mortality-from-chronic-disease/contents/summary>>

⁹ Crosland P, Ananthapavan J, Davison J, Lambert M, Carter R 2019, 'The economic cost of preventable disease in Australia: a systematic review of estimates and methods' Australian and New Zealand Journal of Public Health. 43(5), available at: <<https://pubmed.ncbi.nlm.nih.gov/31390112/>>.

2.1.2 The intent of ‘enabling consumers to make informed choices’ has evolved over time

One of the core goals for FSANZ is the provision of adequate information relating to food to enable consumers to make informed choices (s 3(c)).

It is understood that the original intent of this goal was to ensure that consumers had access to food safety information such as the potential allergen alerts. Over time however, consumers have used food labels to inform their purchasing and consumption behaviours for a variety of reasons including dietary preferences, environmental concerns or to support local businesses.

This change has created some complexities about how the Act interfaces with consumer law, where consumer protection and choice are the central focus of regulation. This has contributed to the confusion seen over the years about the right regulatory scheme to use to progress certain objectives; country of origin labelling and palm oil use disclosures are examples of regulated information that were debated before ultimately being managed within consumer laws.

2.1.3 FSANZ must have regard to the desirability of an efficient and internationally competitive food industry, but this is not an explicitly stated goal for FSANZ in s 3 of the Act

The Terms of Reference for the Review specifically recognise the importance of the food industry to regional communities and the broader economies of both Australia and New Zealand.

Supporting trade is not currently an explicit core goal for FSANZ as set out in s 3 of the Act. Though one of FSANZ’s goals in this provision is the “establishment of common rules for both countries and the promotion of consistency between domestic and international food regulatory measures” (s 3(d)), this does not make explicit reference to trade or an internationally competitive industry. The desirability of an efficient and internationally competitive food industry is one of the factors to which FSANZ “must have regard” in the development of food regulatory measures (see below).

Some stakeholders have reported that this is a missed opportunity and that by including trade objectives in s 3, there may be a greater impetus to support industry and innovation. Some stakeholders caution that greater emphasis on trade and industry objectives should not detract from the overarching goal of promoting public health and safety.

2.1.4 There are structural tensions within FSANZ’s objectives when developing food regulatory measures

S 18 sets out FSANZ’s objectives in developing or reviewing food regulatory measures (Table 3).

Table 3 | Objectives of the Authority in developing, reviewing or varying food regulatory measures

S 18 | Objectives of the Authority in developing or reviewing food regulatory measures and variations of food regulatory measures

- (1) The objectives (in descending priority order) of the Authority in developing or reviewing food regulatory measures and variations of food regulatory measures are:
 - a) The protection of public health and safety
 - b) The provision of adequate information relating to food to enable consumers to make informed

choices

- c) The prevention of misleading or deceptive conduct.
- (2) In developing or reviewing food regulatory measures and variations of food regulatory measures, the Authority must also have regard to the following:
 - a) The need for standards to be based on risk analysis using the best available scientific evidence
 - b) The promotion of consistency between domestic and international food standards
 - c) The desirability of an efficient and internationally competitive food industry
 - d) The promotion of fair trading in food
 - e) Any written policy guidelines formulated by the Forum on Food Regulation for the purposes of this paragraph and notified to the Authority.

The legislation currently requires FSANZ to develop draft regulatory measures such as food standards where they align with the objectives set out in s 18(1).

As part of that process, they 'must have regard' to five key factors, including any written policy guidelines formulated by the Forum (s 18(2)). Importantly, ministerial guidelines are not binding on FSANZ and each of the factors must be considered with equal weight. Stakeholders have raised concerns that this can create tensions when some of these factors may be in conflict; for example, a ministerial guideline may be at odds with the desirability of an efficient and internationally competitive food industry (see the example at Table 4).

Upon drafting a regulatory measure, FSANZ refers the matter to the Forum for ratification, however the Forum can reject the draft by 'registering their concerns' (s 86). The Forum is not obliged to 'have regard' to the same factors when registering their concerns or meet any criteria in the Act to reject a draft regulatory measure¹⁰. This means that the Forum can put an unequal weight on alignment with ministerial guidelines and the subsequent review process can have significant practical consequences for both FSANZ and the broader regulatory system in terms of the resourcing required and the cost and delay involved in Forum-directed reviews.

Table 4 | Infant formula: an example of where objectives for food regulatory measures conflict

Breastfeeding is widely recognised as the best source of nutrition for babies. However, there are babies who cannot be breastfed, including cases where their mothers are unable, or choose not to do so for various reasons. Infant formula is therefore a critical alternative to breast milk and industry constantly seeks to innovate to create substances that better emulate breast milk.

The infant formula policy guidelines¹¹ include both high order principles, as well as 17 specific policy principles. According to the Act, FSANZ must have regard to these guidelines, as well as each of the other factors set out in S18 of the Act. Ministerial guidelines are not binding on FSANZ.

¹⁰ The Forum is obliged to consider set criteria that are set out in the Food Regulation Agreement. This includes seven criteria: (i) inconsistency with existing policy guidelines; (ii) inconsistency with objectives of FSANZ Act; (iii) does not protect public health and safety; (iv) does not promote consistency between domestic and international food standards; (v) does not provide adequate information to enable informed choice; (vi) is difficult to enforce or comply with; (vii) places an unreasonable burden on industry or consumers.

¹¹ Food Regulation Standing Committee (FRSC) Working Group on the Regulation of Infant Formula Products (2011). *Policy Guideline on infant formula products*. <https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-on-Infant-Formula-Products>

FSANZ recently considered an application and made a decision to permit two optional substances to infant formula products. The decision had given regard to the ministerial guidelines and the Act's objectives. Upon reaching the Forum, however, some jurisdictions expressed concern mostly about one of the 17 specific policy principles in the ministerial guidelines, relating to the need to link a physiological or functional effect to a beneficial health outcome (principle j). As per the criteria set out in the FRA, the Forum asked for a review on the basis that there had not been sufficient regard given to these policy principles. Principle (j) is challenging to meet given that research cannot link individual components of breast milk to health outcomes, despite the wide agreement that breast milk is best for infants and offers many health benefits (yet this is expected from individual substances added to infant formula products).

Overemphasis on specific policy principles may create tensions with other principles in the ministerial guideline, as well as the objectives of the Act, which also require FSANZ to consider international harmonisation and an efficient and competitive food industry.

If additives in infant formula products and other foods is rejected because a health benefit cannot be demonstrated, the favourable trade and economic benefits determined to accrue would be foregone.

2.2 Legislative changes may clarify the Act's objectives

Three reform ideas have been identified to respond to issues relating to the objectives in the Act.

2.2.1 Reform idea 1 –Define 'public health' and 'safety' in legislation to affirm the inclusion of long-term health and nutrition as a core objective

S 3 and s 18 of the Act could be revised to clarify the intent of 'protection of public health' and 'public health and safety'. This could help to address current ambiguities about the role of FSANZ and food standards to supporting public health objectives and provide greater role clarity. This reform idea could be operationalised through a combination of actions, such as:

- **Amending s 3 of the Act to include a definition of 'protecting public health and safety' that encapsulates both acute and long-term health elements**

The Ministerial Policy Statement on the Interpretation of Public Health and Safety in Developing, Reviewing and Varying Food Regulatory Measures provides one such definition of public health: *"all those aspects of food consumption that could adversely affect the general population or a particular community's health either in the short term or long term, including preventable diet-related disease, illness and disability as well as acute food safety concerns."*

FSANZ's statutory functions could also be amended to reflect their agreed role in relation to public health and safety (described further at Section 3).

- **Aligning wording around public health protection across s 3 and s 18**
Current references to safety and public health protection are not consistent between s 3 and s 18. The former refers to "a high standard of public health protection" while the latter states that FSANZ's primary objective in developing standards is "the protection of public health and safety". These sections could be brought into alignment by broadening s 3 to state "a high standard of *safety and* public health protection."

2.2.2 Reform idea 2 - Recognise trade as a core goal and reframe consumer choice as a factor to which FSANZ 'must have regard'

Changes to s 3 and s 18 to recognise supporting trade as a primary goal for FSANZ may better reflect the importance of a competitive domestic and export food industry for both Australia and New Zealand. Prioritising trade and industry efficiency considerations in FSANZ's development of food standards could help to ensure that all changes give sufficient consideration to potential trade impacts.

Removing references to 'enabling consumers to make informed choices' from s 3 and inserting these into s 18(2) as factors to which FSANZ must have regard may reduce duplication between the food regulatory system and consumer law, while recognising the important intersect between the two schemes.

Changes could include:

- **Amending the Object of the Act in s 3**

This section could read: *The Object of this Act is to ensure a high standard of public health protection throughout Australia and New Zealand by means of the establishment and operation of a joint body to be known as Food Standards Australia New Zealand to achieve the following goals:*

- a. a high degree of consumer confidence in the quality and safety of food produced, processed, sold or exported from Australia and New Zealand*
- b. an efficient and internationally competitive food industry.*

- **Amending the objectives of FSANZ when developing, setting or varying food standards**

This section could read: *The objectives (in descending priority order) of the Authority in developing or reviewing food regulatory measures and variations of food regulatory measures are:*

- a. The protection of public health and safety*
- b. Support an efficient and internationally competitive food industry.*

In developing or reviewing food regulatory measures and variations of food regulatory measures, the Authority must also have regard to the following:

- a. The need for standards to be based on risk analysis using the best available scientific evidence*
- b. The promotion of consistency between domestic and international food standards*
- c. The information required relating to food to enable consumers to make informed choice*
- d. The need to prevent misleading or deceptive conduct*
- e. The promotion of fair trading in food.*

2.2.3 Reform idea 3 – Establish criteria in the Act that the Forum must meet to request a review of a draft regulatory measure

The grounds on which the Forum may request FSANZ to review a draft standard or variation are set out in the FRA and do not directly align with FSANZ's objectives in developing food regulatory measures.

The Act could be amended to legislate criteria that the Forum must meet to request a review, where these criteria could harmonise with the factors that currently guide FSANZ's assessment process, as set out in s 18. For example, criteria to request a review might involve specifying how ministerial guidelines should be taken into account in FSANZ's deliberations.

While outside the scope of this review, there may also be value in the Forum redefining its regulatory and non-regulatory objectives and how these are reflected in ministerial guidelines to support food standards and other measures being used to their full effect.

Discussion questions:

3. To what degree are the current legislated objectives an issue for the system? What are the types of problems that different stakeholder groups face as a consequence?
4. What would be the impact (positive, negative or otherwise) of implementing each of the reform ideas below? How could the outcome specified for each idea best be achieved?
 - Reform idea 1 – Define ‘public health’ and ‘safety’ in legislation to affirm the inclusion of long-term health and nutrition as a core objective
 - Reform idea 2 - Recognise trade as a core goal and reframe consumer choice as a factor to which FSANZ ‘must have regard’
 - Reform idea 3 – Establish criteria in the Act that the Forum must meet to request a review of a draft regulatory measure
5. Are there other potential solutions to problems relating to legislated objectives?

3 Functions

Once the objectives and goals for FSANZ are clarified, there is an opportunity to consider how well its current suite of functions aligns with its statutory remit; and whether FSANZ should undertake additional functions in Australia and/or New Zealand.

3.1 FSANZ's statutory functions could be clarified

In line with the Terms of Reference, consideration has been given to FSANZ's current statutory functions, as well as new roles or functions FSANZ could take on in Australia and/or New Zealand.

3.1.1 FSANZ has a broad range of statutory functions

FSANZ has 20 statutory functions set out in s 13. This provides a broad legislative remit within which the organisation operates. In addition to its core role in developing and reviewing food regulatory measures, FSANZ also has a range of coordination and monitoring roles in Australia, working in consultation with the states and territories, or on its own initiative. These roles include facilitating harmonisation of food laws, coordinating monitoring, surveillance and enforcement, conducting research, coordinating food recalls and developing food education initiatives. FSANZ also can perform similar functions at the request of New Zealand. FSANZ also has several international-facing roles, including participating in international, regional and bilateral negotiations. Table 5 provides a summary of FSANZ's statutory functions.

In practice, FSANZ also undertakes significant project-related work. This includes contributions to the Australian Health Survey, the Australia Total Diet Survey, development of a branded food database and reviewing the modelling of the Health Star Rating calculator.

Table 5 | FSANZ's statutory functions

The Act establishes FSANZ as an independent statutory authority and sets out its functions, including the development and variation of food regulatory measures. FSANZ has 20 distinct functions that are set out in s 13 of the Act and establishes the organisation with different functions in Australia and New Zealand:

1. Core functions undertaken across both nations include development and variation of food regulatory measures, promoting the consistency between jurisdictions and providing information to members of the public about the Food Standards Code. FSANZ also has international facing roles, including participating in international, regional and bilateral negotiations.
2. FSANZ's Australia-only functions including working in consultation or co-operation with States and territories on a variety of issues including food recalls; monitoring, surveillance and enforcement; development of food education initiatives. FSANZ also is responsible for developing assessment policies in relation to food imported into Australia.
3. FSANZ is also empowered to perform functions "at the request of New Zealand" (s 13(1)(p) and s 13(1)(q)).

3.1.2 FSANZ's role could be better defined in some cases

While FSANZ's core role as a standard-setting body is well defined and understood, there is not a shared understanding of its mandate in relation to certain other issues. There is currently ambiguity around

FSANZ's role in supporting broader public health and nutrition objectives beyond acute food safety issues, such as promoting healthy eating and protecting Australians and New Zealanders from diet-related diseases. Within its current remit, FSANZ undertakes work that promotes healthy eating (e.g. through nutrition labelling) and a healthy food supply (e.g. through mandatory folate fortification) but this role is not clearly defined or understood by stakeholders. This ambiguity relates partly to the current statement of objectives in the Act. FSANZ also does not have a clear statutory role in relation to other issues such as food crime, food security and food sustainability.

While existing statutory functions set out in the Act are broad and provide scope for FSANZ to undertake a range of work, there are opportunities to clarify FSANZ's role and suitably 'future-proof' the legislation for roles that FSANZ could undertake in achieving its core objectives.

3.1.3 FSANZ could potentially undertake broader roles or functions to deliver greater value to the system, if appropriately resourced

FSANZ could potentially undertake a broader range of roles and functions in Australia or New Zealand. Comparable bodies in overseas jurisdictions have different remits, including regulatory responsibilities and roles in policy development, that could be considered in the Australian and/or New Zealand contexts recognising the distinct ways that food standards are implemented and enforced in jurisdictions.

This is illustrated in Figure 3 below.

Figure 3 | Roles performed by different actors in food regulatory system (domestic and international)



Stakeholders consulted to date have expressed diverse perspectives on whether FSANZ could undertake a wide range of functions:

- Some stakeholders have noted that FSANZ's technical expertise and breadth of capability could be brought to bear on issues like food safety research, education, communications and interpretation of standards. Some stakeholders have emphasised that FSANZ could play a broader and more explicit role in promoting public health objectives. This role could vary from providing input where requested and proactively advising government on evidence-based options to a broader role in promoting healthy eating and effecting changes to the food supply.

- Other stakeholders have argued that FSANZ should focus on delivering its core business effectively before broadening its remit and note the risk of diluting the organisation's impact. Some stakeholders have voiced concerns that FSANZ's credibility and trusted status as a risk-and science-based standard-setting body could be compromised if it took on additional functions, such as regulatory roles.

3.2 Statutory functions could be amended to reflect FSANZ's agreed scope of practice

Two reform ideas have been identified in relation to FSANZ's defined statutory functions. These could be considered separately or together.

3.2.1 Reform idea 4 - Amend the Act to better reflect the functions FSANZ currently delivers, particularly as they relate to supporting long-term health and nutrition

FSANZ's statutory functions could be updated to align with any changes to the regulatory objectives of the Act. This could better reflect FSANZ's current work as it relates to both acute food safety and longer-term public health and nutrition objectives. This could provide greater clarity about FSANZ's core reasons for being and transparency about the activities on which FSANZ should be focussing effort. This reform idea be pursued in conjunction with Reform idea 1 (above) or considered separately.

This Reform idea could be achieved by adding a range of additional statutory functions to include work that is currently undertaken but is not explicitly captured by existing functions, including:

- conducting research that contributes to the evidence base relating to long term health and nutrition (covering activities undertaken by FSANZ such as contributions to the Australian Health Survey, development of a branded food database and the Australia Total Diet Survey)
- undertake and coordinate critical food safety incident investigations¹²
- provide assistance to industry intending to make applications to create or vary food regulatory measures.

This Reform idea could provide greater clarity and a clear legislative basis for work that FSANZ currently undertakes. A general provision around using FSANZ's knowledge and expertise would also accommodate future functions that FSANZ may perform.

3.2.2 Reform idea 5 – Amend s 13 of the Act to reflect a broader range of functions that FSANZ could deliver now and in the future

FSANZ's statutory functions could be updated to include functions beyond those that it currently performs. This could be considered in conjunction with Reform idea 4. These possible additional functions have been identified from desktop research on overseas comparable standard-setting bodies, previous

¹² FSANZ is currently the secretariat for the bi-national Food Safety Network and its role is to coordinate activities, collate and share information. See *Food Regulation (2019) 'Incident response: Responding to foodborne illness outbreaks'*, available at: <https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/incident-response#:~:text=They%20conduct%20epidemiological%20investigations%20to,is%20the%20source%20of%20illness.&text=FSANZ%20provides%20the%20secretariat%20for,activities%2C%20collate%20and%20share%20information.>>

stakeholder feedback and from the Review's Terms of Reference¹³. For the purposes of the Review it is assumed that any additional functions would be appropriately resourced.

Additional functions could include:

- **A role in emerging issues such as food fraud and food crime.** Food fraud and crime refer to any illegal activity using food, including adulteration, tampering, counterfeiting and theft. These are emerging issues that are increasingly significant, in part due to increasingly integrated global food supply chains. One of FSANZ's core objectives is to prevent misleading and deceptive conduct, but its role in relation to food fraud is not currently defined in legislation.

Some stakeholders have observed that, while criminal investigations in relation to food should be within the remit of law enforcement, FSANZ could have a formal role in providing technical advice or guidance in supporting an investigation. Its statutory functions could be expanded to include *providing advice, guidance, assistance and support at the request of law enforcement agencies to support food fraud and food crime investigations*.

- **Coordinating a centralised repository of information on food safety (being 'the Face of Food Safety').** FSANZ could provide a central repository or hub on its website for information about food safety for consumers and/or industry. To some extent, FSANZ does this already though it does not actively develop industry guidelines and has limited consumer-facing materials. Other organisations such as the *Food Safety Information Council* also provide consumer-focused food safety information. Stakeholders have observed that access to a single consolidated source of information on food safety issues and food standards may be valuable, noting the importance of not duplicating effort.

FSANZ currently has a statutory role to *develop food education initiatives, including the publication of information to increase public awareness of food standards and food labels*. This can only be performed in co-operation with the States and territories. This could be broadened to enable FSANZ to undertake this work *on its own initiative*.

- **Coordinating food safety research.** Some stakeholders identify potential duplication in food safety research between government entities, universities, research institutions and the private sector, and highlight the potential for greater collaboration. This is potentially a more significant issue for Australia. In New Zealand, the *New Zealand Food Safety Science & Research Centre* has been established to provide a 'focal point for food safety science and research' bringing together, government, industry and universities. This may not, however, resolve larger research coordination issues in the bi-national context.

Given FSANZ's technical expertise and extensive domestic and global networks, it could have an Australia-specific or bi-national statutory function to *facilitate collaboration and coordination of food safety research*. This would require a coordinated approach to prioritising research issues and bringing together relevant parties.

¹³ The Terms of Reference for the Review specify consideration of several additional functions, namely: enforcement of food standards (4a), emerging issues such as food fraud and food crime (4b), food safety (4c), coordination of food safety research (4d), communication of food standards to industry and consumers (4e) and undertaking education campaigns in alignment with Priority 1 and 2 of the food regulatory system (4f).

FSANZ currently has an Australia-specific function "to coordinate monitoring, surveillance and enforcement of activities relating to food available in Australia" (S13(f)). FSANZ also has a broader role in Australia and New Zealand to "develop guidelines to assist the interpretation of the Australia New Zealand Food Standards Code" (s 13(c)).

- **Undertaking education campaigns in alignment with other food regulation system priorities.** FSANZ currently has a limited legislative role in Australia in relation to developing food education initiatives in cooperation with the States and territories, including to increase awareness of food standards and food labels. It has not recently exercised this function and does not have a significant education role.

FSANZ could undertake a broader role in developing and/or leading public education campaigns to support food regulation system priorities, related to reducing foodborne illnesses and chronic diseases related to obesity. To enable this, its current function to develop food education initiatives could clarify the scope of food education initiatives to include food safety and public health issues.

Discussion questions:

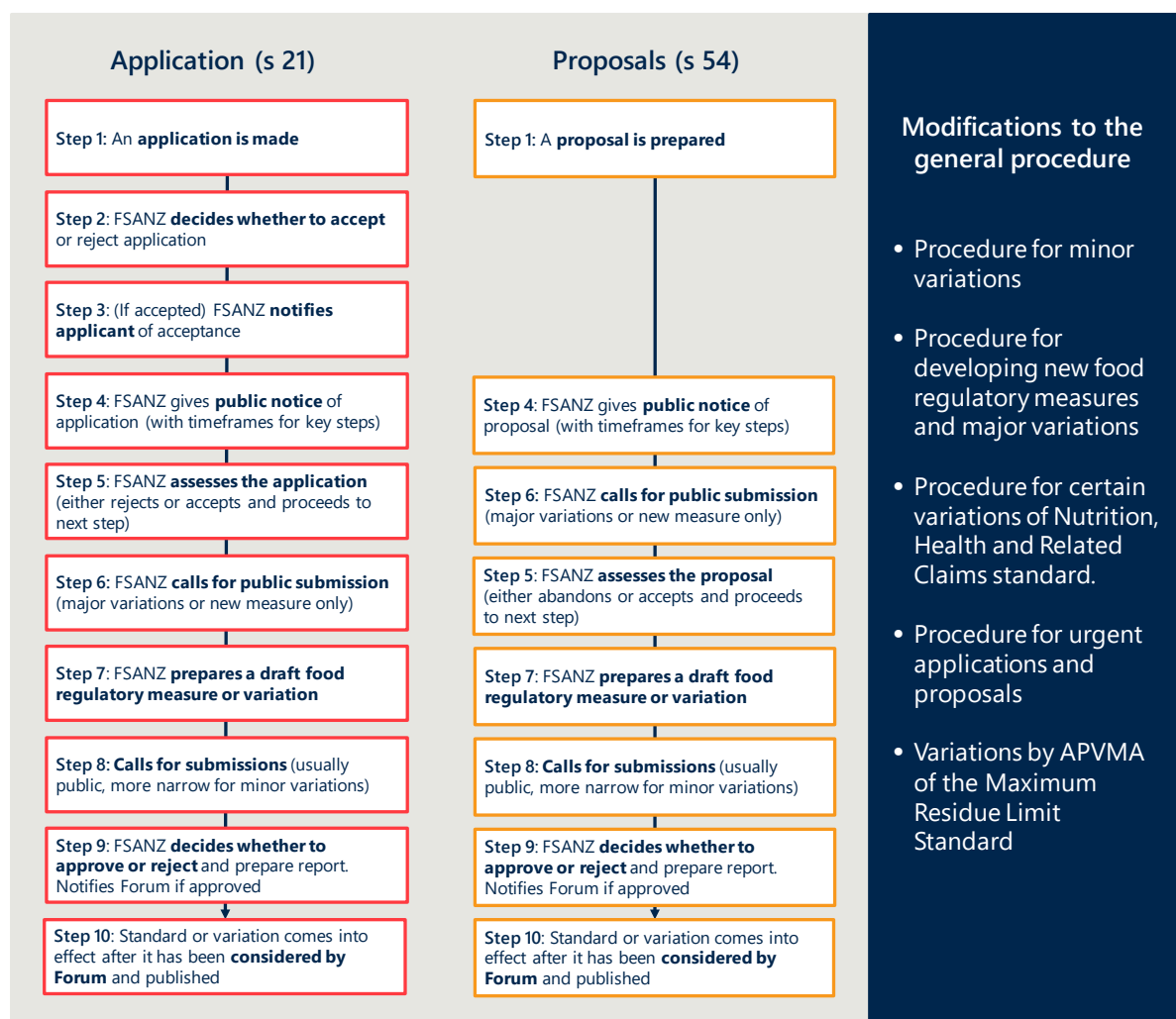
6. To what degree are FSANZ's functions (as currently stated in the Act) an issue for the system? What are the types of problems that different stakeholder groups face as a consequence?
7. What would be the impact (positive, negative or otherwise) of implementing each of the reform ideas below? How could the outcome specified for each reform idea best be achieved?
 - Reform idea 4 - Amend the Act to better reflect the functions FSANZ currently delivers, particularly as they relate to supporting long-term health and nutrition
 - Reform idea 5 – Amend s 13 of the Act to reflect a broader range of functions that FSANZ could deliver now and in the future
8. Are there other potential solutions relating to FSANZ's statutory functions?

4 Legislative processes and decision-making arrangements

Part 3 of the Act sets out processes for making changes to food regulatory measures. FSANZ must follow these processes as written to be compliant with the law.

Food standards are the most commonly used regulatory measure. They are created or changed through two statutory processes – *applications* received by FSANZ that are industry-initiated and *proposals* prepared by FSANZ. The Act includes a ‘general procedure’ for applications and proposals and a series of modified procedures, for instance for major, minor and urgent variations (see Figure 4). FSANZ is subject to statutory timeframes for initial assessment and resolution of applications which vary between 3 and 12 months. There are no statutory timeframes for proposals.

Figure 4 | Process for creating and varying food regulatory measures via applications and proposals



4.1 There are currently limited mechanisms for holistic reviews of standards to ensure they remain suitable and fit-for-purpose

4.1.1 Food standards are exempt from sunset provisions

In Australia¹⁴, most Commonwealth legislation is subject to a sunset regime set out in the *Legislation Act 2003* which provides that the law ceases to have effect after a specific date. This provides an important mechanism to ensure rule-makers consider the ongoing usefulness and appropriateness of regulations.

The standards in the Food Standards Code are legislative instruments under the *Legislation Act* but are currently exempt from sunset provisions (see, for example, s 94 of the FSANZ Act). This reflects the distinct arrangements of the food regulatory system and the cooperation between governments required as part of the bi-national and federated system.

The gradual and iterative development of standards over time (primarily in response to industry-initiated applications) can result in inconsistencies within and between standards. For example, Australia-specific Primary Production standards – which are currently being reviewed by FSANZ – do not provide a consistent approach to managing risk as they have been developed extemporaneously over time for different commodities.¹⁵ A routine regular review of standards that considers their overarching purpose and intent within the Code and food regulatory system may better ensure that they remain fit-for-purpose, outcome-focussed and mitigate risks of unnecessary regulations being introduced over time.

4.1.2 The current approach to reviewing standards is reactive

FSANZ currently conducts reviews¹⁶ of existing standards in response to an application or by raising a proposal. These pathways may not provide a strategic approach to reviewing food standards. For instance, applications are industry-driven and tend to have a specific focus on an issue and there is limited ability to broaden the scope of the application following the initial assessment. Given FSANZ's resourcing constraints and statutory timeframes attached to applications, these tend to receive priority order in the work plan (discussed further at Section 5.2). Consequently, comprehensive reviews of standards initiated by proposals can take many years to assess. For example, the current proposal to revise and clarify standards relating to infant formula, P1028, was prepared in 2013 and is still being progressed.¹⁷

Regular reviews of standards are important to ensure they remain fit-for-purpose and relevant, particularly given evolving industry practices and technologies, government priorities, and consumer preferences, consumption patterns and needs.

Current legislative arrangements for reviewing food standards, coupled with resourcing constraints faced by FSANZ, do not readily allow a big picture perspective on reviews of standards.

Other regulatory systems have more strategic mechanisms in place to review standards. Examples are included in Table 6.

¹⁴ New Zealand regulations are not subject to sunset arrangements.

¹⁵ FSANZ (2019) *Information paper – review of Food standards Code chapters 3 and 4 – Food Safety Management requirements*, available at:

<<https://www.foodstandards.gov.au/foodsafety/standards/review/Documents/Review%20of%20food%20safety%20management%20standards%20-%20information%20paper.pdf>>

¹⁶ Within the standard development process, FSANZ may also be requested by the Forum to undertake a review of a draft standard or variation. This section is not focussed on this form of review.

¹⁷ FSANZ (2017) P1028 Infant formula, available at < <https://www.foodstandards.gov.au/code/proposals/Pages/P1028.aspx>>

Table 6 | Examples of more strategic approaches to reviewing standards

The **National Construction Code (NCC)** which is a performance-based regulatory instrument that sets out minimum performance requirements for the safety and health, amenity, accessibility and sustainability of the built environment in Australia. The Australian Build Codes Board (ABCB) undertakes a strategic review and reform of the code every three years. The three-year amendment timetable is established in the Australian Building Codes Board Intergovernmental Agreement 2020.

Some standards also sunset; for example, the **Victorian Plumbing Regulations 2018** contain plumbing standards, and these sunset 10 years after proclamation. Standards are comprehensively reviewed as part of the development of new regulations.

4.2 A strategic approach to reviewing standards could better future-proof the regulatory framework

Two reform ideas have been identified to support more strategic reviews of food standards. These are not mutually exclusive and could be implemented separately or in conjunction.

4.2.1 Reform idea 6 – Remove exemption of food standards from sunset arrangements

The exemptions that currently exist in the FSANZ Act on sunset food standards could be removed and standards could be subject to regular review. This would provide a clear legislative requirement for standards to be considered and/or updated on a more regular basis. This would provide a scheduled opportunity for more holistic and first principles reviews of standards to ensure their ongoing relevance and appropriateness.

Consideration would have to be given to appropriate processes and the resources required to undertake regular reviews. In addition to resourcing constraints, regular reviews of all standards could be a challenge within the existing cooperative decision-making arrangements.

This reform idea may also present challenges for the bi-national arrangements and New Zealand, where sunset arrangements for legislation are not commonplace.

4.2.2 Reform idea 7 – Resource FSANZ to undertake regular, more holistic reviews of food standards

FSANZ could implement a more strategic approach to the review of standards. This could be coupled with, or considered separate to, removing exemptions of food standards to sunset provisions.

This could be based on an ongoing quality oversight and monitoring role and could include processes involving environmental scans, consultation and data analysis to consider whether a standard is fit-for-purpose in achieving its intended objectives and whether there are opportunities for improvement. This could be led by FSANZ in consultation with key stakeholders, including industry, consumer and public health bodies.

This could be done within its current legislative remit – namely, by raising proposals – or through new statutory processes. Different statutory processes for reviews of standards could provide a more tailored mechanism for identifying and addressing inconsistencies within food standards and opportunities for more effective regulation. FSANZ's statutory function to 'review standards and variations of standards' (s

13(a)) could be broadened to note review to ensure the ongoing relevance and appropriateness of standards.

This reform idea could help to ensure ongoing relevance of standards and provide for a more systematic and strategic approach to reviewing them. It would need to have clearly defined governance arrangements and consultation requirements. This would require additional resourcing for FSANZ. This could be pursued separate to, or in conjunction with, the reform idea above.

Discussion questions:

9. To what degree are the current processes for strategically reviewing standards an issue for the system? What are the types of problems that different stakeholder groups face as a consequence?
10. What would be the impact (positive, negative or otherwise) of implementing each of the reform ideas below? How could the outcome specified for each reform idea best be achieved?
 - Reform idea 6 – Remove exemption of food standards from sunseting arrangements
 - Reform idea 7 – Resource FSANZ to undertake regular, more holistic reviews of food standards
11. Are there other potential solutions relating to the timing of reviews of food standards?

4.3 Prescriptive statutory processes to amend food regulatory measures do not enable a risk-based or flexible response

Approximately half of all proposals and applications made to FSANZ each year relate to minor processing aid amendments, including relating to substances that have been approved in other international food systems¹⁸.

Currently, FSANZ is required to follow a similarly rigid process for all applications and proposals, regardless of the level of risk involved. FSANZ also has limited ability to adjust its approach or change the procedure or timeframes after initial assessment if new information or data becomes available.

This approach represents an inefficient use of FSANZ's limited resources and contributes to the long timeframes in progressing some applications and proposals. FSANZ's workplan currently includes several proposals that were prepared and administratively assessed many years ago.¹⁹ It also includes several applications received prior to 1 October 2007 which are 'on hold'.²⁰

The time, effort and cost associated with applications can represent a barrier to innovation for industry, including because of delays in bringing new products to market. This can also deter prospective applicants from seeking to change the food standards. Where the compliance costs associated with making applications are disproportionate to the associated risks, this provides impetus for considering more streamlined processes.

¹⁸ FSANZ (2020) *A position paper on FSANZ's resourcing*. Unpublished position paper.

¹⁹ For example, P1024 – Revision of the Regulation of Nutritive Substances & Novel Foods was prepared in November 2012 and P1028 – Infant Formula was prepared in July 2013. See FSANZ (2020) Food standards development work plan, available at: <<https://www.foodstandards.gov.au/code/changes/Documents/Food%20standards%20development%20Work%20Plan.pdf>

²⁰ Ibid

4.3.1 The full suite of regulatory measures is not being leveraged

FSANZ has several different regulatory instruments to achieve its objectives. The Act allows FSANZ to develop *food regulatory measures* which comprise food standards and codes of practice. FSANZ can also develop guidelines to assist interpretation of the Food Standards Code on its own initiative or in consultation with the Australian States and territories and other bodies (s 13(c)).

Currently, FSANZ almost exclusively uses food standards as a legislative instrument. It makes available an Application Handbook (authorised under s 23) but does not develop codes of practice. FSANZ makes some non-legally binding guidelines available on its website, including 'User guides to the Food Standards Code', though some stakeholders have noted that this may represent a currently under-utilised resource.

Guidelines and codes of practice provide different regulatory instruments that could be used to address specific issues or challenges that do not warrant the time, resources and/or rigour of processes required to develop or vary a standard. As it is, the Act provides for FSANZ to make guidelines and codes of practice as well as food standards; FSANZ can make changes to guidelines without external consultation, and it can make changes to codes of practice following consultation (limited or broad, depending on magnitude of the change) but do not require ratification from the Forum.

Other regulatory schemes also make use of voluntary codes of practice, for example, the Australian Competition and Consumer Commission (ACCC) facilitates the development of industry-led industry codes. The value of these instruments is that they can generate a significant degree of buy-in or sense of ownership from within the regulated sector, and do not need to go through the same rigorous endorsement processes as other instruments.

4.3.2 Decision-making arrangements for regulatory measures are unusual

Under the current legislation, all draft standards or variations must be approved by the FSANZ Board before being ratified by the Forum. This arrangement is unique to the food regulatory system; most standard-setting bodies have statutory powers to set and amend standards without ministerial involvement (see examples in Table 7 below)²¹. Indeed, currently the Australian Pesticides and Veterinary Medicines Authority (APVMA) is able to change the Maximum Residue Limits standard of the Food Standards Code directly, without oversight of the Forum.

Table 7 | Decision-making arrangements for standards in select other regulatory schemes

Australian Pesticides and Veterinary Medicines Authority (APVMA)

The APVMA has co-regulatory responsibility with FSANZ in Australia for the Maximum Residue Limits standard contained in the Food Standards Code. Under current legislative arrangements, the APVMA has the power to amend Schedule 20 of the Code in certain instances directly, without sign-off by the Forum or statutory requirements of application or proposal processes.

Australian Building Codes Board (ABCB)

The ABCB is responsible for developing and maintaining the National Construction Code (NCC) which is a performance-based regulatory instrument that sets out minimum performance requirements for the safety and health, amenity, accessibility and sustainability of the built environment in Australia.

The Building Ministers' Forum comprises the Australian Government, State and Territory ministers with responsibility for building and construction. The BMF sets the strategic policy direction for the ABCB and

²¹ The National Cabinet Review of COAG Councils and Ministerial Forums is underway at the time of writing. Recommendations from this review may fundamentally reconceive the existence or role of the Forum in the food regulatory system.

can provide directions to the ABCB in relation to the code, but the ABCB is responsible for developing and maintaining codes and standards through the NCC.

Standards New Zealand

Standards New Zealand is a business unit within the Ministry of Business, Innovation and Employment which specialises in managing the development of standards. The Standards New Zealand Executive have statutory powers under the *Standards and Accreditation Act 2015* to approve new or varied standards. It must advise relevant Ministers of proposals to amend, revise, archive or replace standards that are cited in legislation; however, Ministers are not involved in their sign-off.

The Act is also prescriptive about decision-making duties within FSANZ, with sign-off of regulatory measures listed as a non-delegable duty for the FSANZ Board, which can add an additional complexity to get signatures for all Board members.

4.4 Legislative changes could support more risk-based processes and decision-making

Two reform ideas have been identified to address issues relating to legislated processes. These are not mutually exclusive and could be implemented separately or in conjunction.

4.4.1 Reform idea 8 – Reframe legislation to support more agile, risk-based processes

This reform idea reconceptualises how changes to food standards will be made, with risk being a key driver of process. A move towards recognising categories of risk will allow FSANZ to expedite routine or low-risk amendments while focusing limited resources to carefully consider and assess high risk amendments that may have wide ranging food safety, social or economic impacts.

Supporting more agile, risk-based processes and decision-making could involve several activities, such as:

- **Transferring much of the detail from the Act into the FSANZ Regulations** – Part 3 of the Act could be stripped back to its essentials by moving content into the Regulations. The Act could include general provisions to *provide for applications or proposals to be made to amend food standards* and *provide for FSANZ and the Forum to be involved in ratifying amendments*. Other requirements and details could be moved to the Regulations. The advantage of this approach is the relative ease with which legislation could be updated; unlike primary legislation, changes to Regulations do not require consensus at parliamentary debate.²²
- **Establishing a policy framework for use of the hierarchy of legislative instruments available to FSANZ** – This might involve creating a resource to guide decisions about the instrument that can most appropriately deal with the identified problem. Implementing such a framework may result in greater uptake of codes of practice (mandatory and voluntary) and guidelines, which can be created and amended in more agile and responsive ways.

²² Changes to FSANZ Regulations require some level of sign off from both Australia and New Zealand. The Joint Food Treaty includes a commitment to consultation between the member states regarding food legislation, in particular that “Australia shall not introduce any amendments to the Australian legislation establishing the Authority, or move government amendments to that legislation, without effective consultation with New Zealand during their development.”

- **Redefining processes to develop or vary regulatory measures based on risk** – This could mean creating outcome-based processes within the legislation that reflect a level of consultation and assessment commensurate with the risk involved and provide sufficient flexibility to adjust the approach or procedure based on new information.

'Risk' might be determined through a non-legislated framework and reflect criteria such as those shown in Table 8.

Table 8 | Indicative risk framework

#	Criterion	Key question
1	Alignment with strategic priorities	1. Is the application/proposal a strategic priority (e.g. for innovation, safety, health) as determined by Forum?
2	Subject matter / Expertise	2. What expertise is required to make decisions? (e.g. technical scientific capability or broader policy issue)
3	Extent of risk	3. How significant is risk to public health or safety / how complex is the risk assessment?
4	Scope of impact	4. How broad reaching and immediate are social, economic and health impacts ?
5	Existing evidence	5. Is there a strong and relevant evidence-base in existence?

Once criteria and thresholds for risk are agreed, processes and decision-making arrangements could be aligned to the risk level (including the level of public consultation involved). For instance:

- amendments that are considered 'low risk' might follow a process similar to that currently set out for minor variations
- medium risk amendments might follow a process similar to that set out for codes of practice
- high risk applications might follow a process similar to major variation
- provision for urgent amendments could be retained.

Should a risk framework be agreed, separate work would be required to determine the decision-making arrangements for triaging applications and proposals and deciding an overall risk profile. This may need to be regularly reviewed to ensure that it remains up-to-date and fit-for-purpose, particularly as successive governments and FSANZ leadership may have different approaches or appetites to risk management.

4.4.2 Reform idea 9 – Redefine the decision-making arrangements to support timelier and more efficient sign-off of regulatory measures

The risk framework could be used to distinguish between amendments that are highly technical in nature and which have low-regulatory impact and which may be of limited relevance to the Forum as the system's policy steward (for example, processing aid amendments); compared to high-impact amendments that have broad-ranging political and economic consequences, which are likely to be of key interest to Ministers (for example, the recent proposal to mandate pregnancy warnings on alcohol). The Act could then permit for decisions about draft food regulatory measures to be made efficiently by the most appropriate decision-makers, commensurate with risk. Changes could include:

- **Providing for both the Forum and the FSANZ Board to delegate decision-making about food standards** – The Act could be amended to enable the FSANZ Board to delegate decision-making responsibilities for draft standards or variations, and/or for the Forum to delegate decision-making following Board approval. This could be a general power or could be constrained to apply to 'low' and 'medium' risk changes.

Decisions delegated by the Forum could be made by each minister - or *their* delegate - with each jurisdiction ultimately casting a vote on an amendment. This means that in some jurisdictions, the Minister him or herself would vote, whereas in other jurisdictions another person, such as a head of a government department, might vote. How these votes are treated as a 'Forum decision' would align with arrangements set out in the FRA.

Decisions delegated by the FSANZ Board could be made by FSANZ's CEO.

- **Provide for the Forum to delegate decision-making to FSANZ for more low risk, technical amendments** - This change could remove the Forum from some decision-making arrangements (e.g. routine processing aid amendments) and enable FSANZ to ratify amendments in a timelier way.

Discussion questions:

12. To what degree are the current statutory application and proposal processes an issue for the system? What are the types of problems that different stakeholder groups face as a consequence?
13. What would be the impact (positive, negative or otherwise) of implementing each of the reform ideas below? How could the outcome specified for each reform idea best be achieved?
 - Reform idea 8 – Reframe legislation to support more agile, risk-based processes
 - Reform idea 9 – Redefine the decision-making arrangements to support timelier and more efficient sign-off of regulatory measures
14. Are there other potential solutions relating to streamlining current legislative process to develop or vary regulatory measures?

4.5 Additional pathways to develop or vary food standards could be beneficial

The Act currently requires FSANZ amendments to be progressed either via applications or proposals.

4.5.1 Current statutory processes provide limited ability to use international standards and risk assessments

In developing standards, FSANZ is required by law to have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence
- the goal of consistency between domestic and international standards.

Within this context, FSANZ considers existence and relevance of international standards in its work, and routinely makes use of risk assessments from abroad. FSANZ also works with overseas jurisdictions and international bodies in undertaking its work (see Table 9). However, it is generally not possible to adopt or harmonise with international standards outside of statutory application or proposal processes. This means

that, for example, there are limited opportunities to fast track or expedite an application or proposal that is based on a well-established and evidenced standard or assessment from an overseas jurisdiction.

As a result of these constraints, the international food safety evidence base is arguably underutilised in FSANZ's assessments. This can have adverse impacts for industry – because of the time it takes to bring products to market in Australia and/or New Zealand – as well as flow on consequences for consumers in terms of the range of food products available to choose from. Industry stakeholders have noted concerns and frustrations around the time that it can take to introduce new products to market that are available in other reputable markets with rigorous and credible food regulatory systems.

Table 9 | Examples of FSANZ's work with other jurisdictions

Risk assessment sharing for GM foods between FSANZ and Health Canada

Since 2013, FSANZ and Health Canada have worked together on the safety of genetically modified (GM) foods. A formal agreement is in place to facilitate the sharing of safety assessments of food derived from genetically modified organisms. This helps to reduce duplication and share scientific expertise.

This initiative is in a pilot phase for assessing safety of GM foods that are not authorised in either jurisdiction. Health Canada conduct the assessment which is then reviewed by FSANZ. This can form basis of joint approval of a GM food in Canada, Australia and New Zealand.²³

FSANZ also has formalised agreements for information exchange (including through Memoranda of Understanding) with counterparts in many countries, including the USA, Europe, UK, Japan and Korea.²⁴

FSANZ's involvement in developing Codex standards

FSANZ contributes to international standards development in a range of ways, notably through its participation in the Codex Alimentarius Commission (Codex) – the international food standards setting body. FSANZ contributes to the work of many Codex committees and currently leads the Australian delegation to several committees and groups, including those related to food additives, contaminants, food hygiene, antimicrobial resistance, and nutrition and foods for special dietary uses.

4.5.2 An enhanced role for industry through self-assessments would require appropriate regulatory oversight and safeguards

Food businesses have a vested interest in assuring that the food products they sell are safe for consumers. This interest underpins substantial research and analysis that goes into food product development. FSANZ's current approach to ensuring safety of new food products is through a desktop review of evidence provided as part of an application to change food standards. This process is very rigorous but could be differentiated more based on risk.

There may be benefit in providing for more streamlined pathways for making changes to food standards or introducing new food products that draw on well-established and evidenced international standards and/or risk assessments. This could include a greater role for industry self-certification for products that pose a low risk or streamlined application pathways with shorter statutory timeframes.

There is a growing trend internationally for modern regulatory systems to take a partnership approach with industry to establish shared goals for the system. For example, Canada has proposed to pilot the

²³ FSANZ (2020). *Canada and FSANZ working together on GM food safety*.
<https://www.foodstandards.gov.au/science/international/Pages/gm-food-safety.aspx>

²⁴ FSANZ (2014). *Promoting international harmonisation of Food Standards*.
<https://www.foodstandards.gov.au/publications/Pages/International-activities-and-engagement.aspx>

concept of 'Ethical Business Regulation', which is a regulatory approach that recognises that industry has a vested interest (by way of reputation, profits/sales and growth) to ensure risks are well managed²⁵.

Appropriately leveraging this interest can lead to stronger working relationships between regulators and industry and minimise duplication of risk management efforts. The Canadian Food Inspection Agency proposes to establish "champion" food businesses, which whom they will collaborate to explore how risk management responsibilities can be shared better between regulators and food businesses.²⁶

Within the Australian and New Zealand context, the potential benefits for industry of more streamlined pathways include more timely amendments to food standards, reduced time to bring products to market and reduced time, effort and costs associated with applications. Potential drawbacks include that more support may be required for food businesses to understand how to utilise streamlined pathways and their associated obligations.

Any changes to partner more effectively with industry would need to be balanced with appropriate statutory controls and regulatory oversight.

Currently, FSANZ's regulatory attention is focused on pre-market approval (through considering applications and proposals to change standards). Additional pathways could partially shift FSANZ's oversight role towards post-market surveillance and quality assurance. An example of this post-market focus in another regulatory scheme can be taken from the TGA's *lifecycle approach* to regulating medical devices (see Table 10).

Table 10 | The TGA's risk-based and lifecycle approach to regulating medical devices in Australia

The TGA is responsible for regulating medical devices in Australia under Chapter 4 of the *Therapeutic Goods Act*. Medical devices must meet essential principles (related to safety and performance characteristics) to be supplied in Australia. This can be demonstrated through a 'conformity assessment' which is a procedure used and evidence generated by a manufacturer to demonstrate that a medical device is safe, fit-for-purpose and performs as intended.

The TGA has a five-part classification system for medical devices; the lowest risk, Class 1 devices, are not assessed by the TGA prior to inclusion on the Australian Register of Therapeutic Goods (ARTG). High risk devices have specific regulatory requirements, for instance the TGA must issue a conformity assessment for some devices (rather than a comparable overseas regulator).

The TGA has a life-cycle approach to regulation that spans both pre-and post-market approval:

- **pre-market activities** include a conformity assessment which is led by a manufacturer through a systematic and ongoing examination to determine that the device is safe and performs as intended
- **market authorisation** involves inclusion in the ARTG
- **post-market monitoring activities** include requirements for manufacturer to monitor ongoing performance and safety and notify TGA of major issues. The TGA also can conduct random and targeted assessment of devices.

The TGA's life-cycle approach to regulation places greater emphasis on regulation after inclusion on the ARTG for lower risk categories of medical devices. This approach aims to ensure that the level of regulation matches the risks posed by medical devices. Notably, the TGA is currently implementing a series of medical device regulatory reforms to increase the rigour of pre-market assessments of higher risk medical devices, to assure their quality, safety and performance.

²⁵ Canadian Food Inspection Agency "Targeted Regulatory Review: Agri-food and Aquaculture Roadmap" 2019 from < <https://www.inspection.gc.ca/about-the-cfia/acts-and-regulations/forward-regulatory-plan/agri-food-and-aquaculture-roadmap/eng/1558026225581/1558026225797>>

²⁶ Notably, unlike FSANZ, the Canadian Food Inspection Agency is responsible for enforcement of food standards.

While the TGA has a regulatory role in enforcing the law, unlike FSANZ, the regulatory model for medical devices shows how oversight and regulatory attention can encompass both pre and post-market approval and the importance of appropriate risk management and statutory controls.

4.6 New pathways to amend food standards may support a more timely and responsive regulatory system

Three reform ideas relating to new pathways to amend food standards have been identified. These are not mutually exclusive and could be implemented separately or in conjunction.

4.6.1 Reform idea 10 – Provide for FSANZ to adopt or accept risk assessments from overseas jurisdictions

FSANZ's ability to use risk assessments from other jurisdictions could be enhanced by creating statutory authority for FSANZ to recognise and adopt international risk assessments. This would apply to applications and proposals. FSANZ can currently do this in a limited way as part of considering the weight of evidence for establishing or varying a standard but has little ability to routinely adopt risk assessments in its work. The Act could be amended to enable FSANZ to formally recognise and adopt the assessment and determinations of 'overseas bodies' (with appropriate statutory controls). This could be limited to specific international bodies (such as Codex) or specific assessments (such as chemical risks assessments undertaken by the Joint Food and Agricultural Organization of the United Nations / World Health Organization Expert Committee on Food Additives) or could be a more general power. A similar provision was introduced to the Therapeutic Goods Act to make market-approvals for medical devices more efficient (see Table 11).

This could help to promote industry innovation, reduce data requirements for applicants and realise efficiencies by reducing current duplication. Careful consideration of applying an appropriate Australia/New Zealand-specific risk assessment would need to be considered, especially where there are divergences in scientific opinions. This would require information sharing and data arrangements to promote confidence in overseas risk assessments.

Table 11 | Medical device regulation – conformity assessment procedures and overseas regulators

Under the Australian regulatory scheme for medical devices, manufacturers can use a **conformity assessment** to demonstrate that a medical device is designed and produced to be safe, fit for purpose and perform as intended. Conformity assessment is the systemic and ongoing examination of evidence to ensure that a medical device complies with essential principles and other legislative requirements. Evidence of a conformity assessment must be held before a device can be included in the ARTG.

Some medical devices must have a TGA conformity assessment certificate. Other devices can be included in the ARTG based on evidence from a comparable overseas regulator or assessment body. Under the *Therapeutic Goods Act* the Secretary may designate a body to be an '**overseas regulator and/or assessment body**' that can provide evidence used to inform inclusion on the ARTG.

These changes were introduced as a result of the Expert Panel Review of Medicines and Medical Devices Regulation which recommended better utilisation of overseas approvals of medical devices.

4.6.2 Reform idea 11 – Enable FSANZ to adopt international standards

The Act could be revised to allow FSANZ to adopt or incorporate international standards into the Food Standards Code outside of the current proposal pathway through a more streamlined approach. Options to adopt or incorporate international standards could vary with the level of oversight tailored to the risk presented by the particular standard. This could include a range of potential pathways including:

- routine consideration or adoption of newly developed Codex standards or standards from overseas jurisdictions when they come into effect
- mutual recognition arrangements with other comparable jurisdictions
- adoption of standards where accompanied by an appropriate and suitable risk and safety assessment (undertaken by FSANZ).

This reform idea could improve the timeliness to make changes to food standards where there is a strong existing evidence base and could help to support consistency between domestic and international standards. It could also lead to more effective resource allocation by introducing more tailored pathways for more routine adoption of international standards.

Resourcing requirements to ensure that standards stay up-to-date and relevant would need to be considered. Clear and appropriate governance arrangements and processes for these pathways would need to be agreed that support timely decision-making and provide sufficient opportunities for consultation and engagement.

4.6.3 Reform idea 12 – Create industry-led pathways to expedite applications and bring new products to market

This reform idea would create streamlined pathways for changes to food standards that are supported by well-established international standards and risk assessments. This reform idea would enable industry to bring new food products to market in Australia and New Zealand more quickly and would shift oversight more towards post-approval monitoring and quality assurance.

This reform idea could be tailored to different risk levels and could include:

- **a greater role for industry self-certification**, including 'listing' low risk products in the Food Standards Code in a similar manner to the TGA's listed medicines (see Table 12)
- **a streamlined application pathway** with shorter statutory timeframes, without the Forum's sign-off, for suitably low-risk standards where a safety assessment from a comparable jurisdiction is produced as part of the application
- **an initial safety assessment prior to market entry** with the ability to conduct a more fulsome assessment after a product is introduced. This could be similar to Canada's *market authorisation* regime (see Table 13).

These pathways would require appropriate statutory requirements on food businesses to hold and submit relevant information and appropriate powers for FSANZ to request or compel information to be provided. This reform idea could support greater innovation and efficiency and supports alignment with international standards, however suitable statutory controls would be required to determine appropriate applications or standards that could use this pathway.

Table 12 | Three-tiered risk-based framework for complementary medicines

Following amendments to the Therapeutic Goods Regulations in 2018, the TGA introduced a **three-tiered**

risk-based framework for complementary medicines in Australia which tailor regulatory oversight to different levels of risk. This was the product of 2018 amendments to the *Therapeutic Goods Regulations* that established a new intermediate pathway for a complementary medicine to enter the ARTG.

These pathways are:

- **listed medicines** may be listed in the ARTG without undergoing pre-market assessment by the TGA after self-certification by sponsors that legislative requirements are met.
- **assessed listed medicines** are products that are composed of ingredients from a list set and approved by the TGA, but which make claims that they are indicated for ailments that fall outside the list of permitted indications. Assessed listed medicines may be included in the ARTG following self-certification of quality and safety and pre-market assessment for efficacy evidence by the TGA.
- **registered medicines** are registered in the ARTG after successful pre-market assessment of quality, safety and efficacy.

Table 13 | Market authorisation regime in Canada's food regulatory system

In Canada, the Minister for Health can issue a 'market authorisation' under the *Food and Drug Act 1985* that exempts products from specific legislative requirements in the Act and Regulations. This allow a food product that is non-compliant with certain regulatory requirements to enter the market when it is in the interest of public health to do so. The scheme includes different instruments – *temporary* and *interim* market authorisations – that allow a product to be sold while relevant data is collected and analysed and amendments to Food and Drug Regulations are made.

The market authorisation regime is a tool to help government more rapidly authorise or amend approvals of products with beneficial health impacts. Market authorisations are rules of general application; they apply to the entire food industry as opposed to a single company. Market authorisations are subject to general regulatory requirements that require Health Canada to follow a formal regulatory process.

Discussion questions:

15. To what degree is the current approach to using only applications and proposals to develop or vary food standards an issue for the system? What are the types of problems that different stakeholder groups face as a consequence?
16. What would be the impact (positive, negative or otherwise) of implementing each of the reform ideas below? How could the outcome specified for each reform idea best be achieved?
 - Reform idea 10 – Provide for FSANZ to adopt or accept risk assessments from overseas jurisdictions
 - Reform idea 11 – Enable FSANZ to adopt international standards
 - Reform idea 12 – Create industry-led pathways to expedite applications and bring new products to market
17. Are there other potential solutions relating to additional pathways to develop or vary food regulatory measures?

5 Partnerships

As the standard-setting body, FSANZ interfaces with a number of other entities. These include: the Forum in its role as system steward for food policy and strategy; regulatory enforcement agencies which involve a variety of institutional arrangements across Australia and New Zealand; and other regulatory bodies²⁷, including the Australian Therapeutic Goods Administration and the New Zealand Medicines and Medical Devices Safety Authority (a business unit within the Ministry of Health).

There are known tensions at some of these interfaces, as well as potential opportunities to work even more effectively through a partnership approach. These three interfaces are discussed further below.

5.1 Governments' and FSANZ's priorities are not always aligned

5.1.1 FSANZ and the Forum do not always have a shared vision of priorities

FSANZ is an independent statutory authority that works within an integrated food regulatory system in close connection with the Forum. In addition to its role as the decision-maker on all changes to food standards, the Forum can request FSANZ to raise proposals or undertake a review of a draft standard or variation. The responsible Minister²⁸ can also request FSANZ to take on additional project work, such as its current work relating to Health Star Ratings.

Earlier feedback from government stakeholders has suggested that Ministers are sometimes frustrated by the time it takes for proposals to be progressed and finalised. Similarly, FSANZ stakeholders have reported challenges in taking on an increasing number of Forum-directed projects, with little discussion or agreement about items that can come off its workplan. As discussed further in Section 6, FSANZ has reported significant resourcing challenges to progress proposals and project work while also meeting their statutory timeframes relating to applications.

FSANZ and the Forum often have distinct priorities and interests, and both parties have responsibilities to progress their priorities and obligations.

Alternative arrangements could be considered that enable joint priority setting between FSANZ and the Forum. These could focus on establishing a regular two-way dialogue to agree priority work given available resources and FSANZ's statutory requirements. Such arrangements would need to ensure adequate independence for FSANZ in delivering its workplan and an appropriate separation of policy development and standard-setting. Other mechanisms to enable greater connectivity between standard-setting and policy development could also be considered.

²⁷ The food regulatory system interfaces with a number of other regulatory schemes, including consumer law, biosecurity, agriculture and animal welfare and border control. This scoping paper has focused on the food-medicine interface as this is specifically referenced in the Terms of Reference.

²⁸ Currently the Australian Minister for Health as set out in the Common of Australia Administrative Arrangements Order.

5.2 Legislative and operational reforms could improve alignment of policy development and standard-setting

Two reform ideas to address issues related to misalignment between policy development and standard-setting have been identified. These could be considered separately or in conjunction.

5.2.1 Reform idea 13 – Facilitate joint agenda setting between FSANZ and the Forum

FSANZ and the Forum could implement routine joint priority setting mechanisms to regularly agree priorities, including both general strategic priorities and priority changes to food standards. This could, for instance, consist of annual planning where members of FSANZ and the Forum come together to agree the proposals and other project work that will be progressed as part of FSANZ's workplan with a view to removing or abandoning lower priority items. (Joint priority setting might focus solely on the component of FSANZ's workplan with capacity allocated to proposals and project work – it should not displace the progress of applications, which are subject to statutory timeframes).

5.2.2 Reform idea 14 – Amend statutory timeframes to support more strategic prioritisation of work

FSANZ's priority work is driven in large part by the statutory timeframes associated with industry-led applications (discussed further at Section 6.3). Timeframes to which FSANZ is subject in developing or reviewing food regulatory measures could be changed to support more strategic prioritisation of work. This could include through:

- **Establishing timeframes for proposals on a case-by-case basis.** The Act could be amended to enable timeframes to be established within which a proposal should be assessed and completed. This would likely be on a case-by-case basis given that the scope of work involved in a proposal can vary significantly. This could be set by FSANZ in consultation with the Forum, with appropriate flexibility to adjust based on new information. This could help to mitigate issues around the current prioritisation of applications by providing a commensurate mechanism to prioritise proposals. This reform idea would require additional ongoing funding for FSANZ, as it risks exacerbating existing resource constraints faced by FSANZ by imposing additional workload pressures.
- **Creating more flexibility around statutory timeframes for applications.** There are currently limited legislative provisions for FSANZ to change its procedure or adjust its approach and timing for applications based on new information and data. There is also limited ability for FSANZ to 'stop the clock' on the statutory timeframe. This inflexibility can contribute to the prioritisation of applications over proposals.

Discussion questions:

18. To what degree is the current alignment between policy development and standards setting an issue for the system? What are the types of problems that different stakeholder groups face as a consequence?

19. What would be the impact (positive, negative or otherwise) of implementing each of the reform ideas below? How could the outcome specified for each reform idea best be achieved?
- Reform idea 13 – Facilitate joint agenda setting between FSANZ and the Forum
 - Reform idea 14 – Amend statutory timeframes to support more strategic prioritisation of work
20. Are there other potential solutions relating to agreeing system priorities between FSANZ and the Forum?

5.3 Inconsistent interpretation and enforcement of food standards is an enduring issue for the system

Food standards are outcomes-based. This is consistent with *performance-based* regulatory models that specify required outputs and outcomes, rather than inputs. This is increasingly common in modern regulatory frameworks and aims to provide a degree of freedom and flexibility to regulated entities in how to ensure compliance, to support innovation and reduce regulatory burden.

Some stakeholders have reported that the outcome-based nature of food standards is a strength of the system and consider this approach to be especially helpful for large-scale food producers or processors. Such businesses generally have resources to access legal advice to understand their obligations and can structure their operations flexibly based on this advice. However, government stakeholders and industry bodies report that small food businesses including sole traders, who may not have ready access to independent legal advice, have struggled and seek more definitive advice on how to comply with food standards.

One of FSANZ's statutory functions is to issue guidance materials relating to food standards, however much of the information currently available is legalistic, complex or generic to food businesses of all sizes.

Enforcement of food standards is conducted through diverse institutional arrangements (see Figure 5) and, in Australia, are loosely based on model law provisions set out in the FRA.

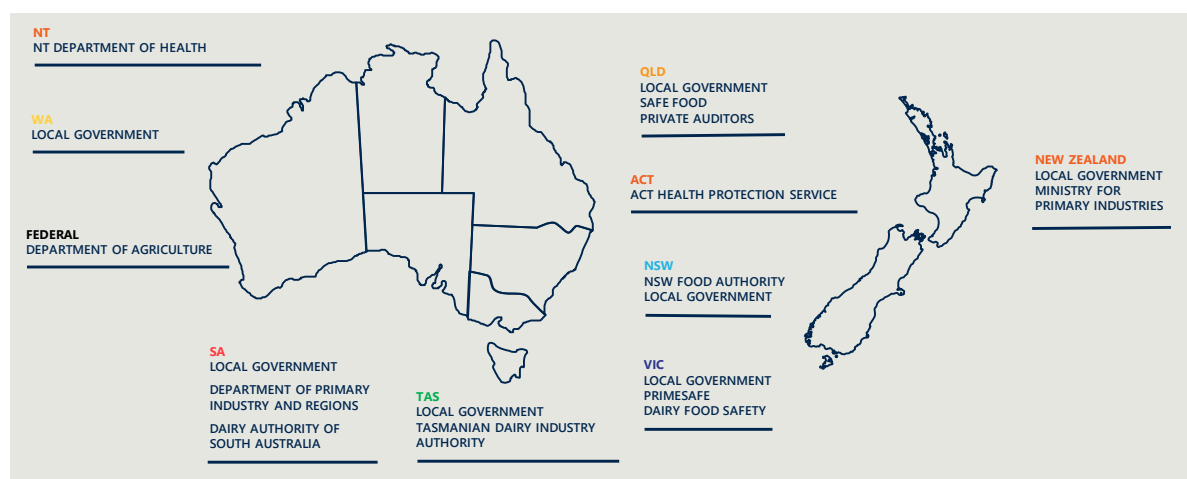
The Implementation Subcommittee for Food Regulation (ISFR) has an important role to facilitate common approaches to implementing food standards through development of guidelines. The ISFR is a sub-committee of the Food Regulation Standing Committee (FRSC; which supports the Forum) and includes representatives from the Australian and New Zealand governments, Australian state and territory governments and the Australian Local Government Association.

The ISFR, along with jurisdictional regulators, are reported to have invested significant resources into creating education materials for food businesses, but interpretations of how the food standards apply are varied, leading to a lack of consistency and duplication of effort. As a result, many small food businesses struggle to understand what they must do to meet their regulatory requirements.

Differences in interpretations is a pronounced issue for Australian businesses, particularly those that trade across state and territory borders and who may face additional costs in adapting their whole production and distribution chain to meet the most rigorous compliance requirements across the jurisdictions in which they operate.

Interpretive uncertainty is less of an issue for New Zealand food businesses, as all enforcement activities are carried out by the MPI. For New Zealand food businesses that export to Australia, however, inconsistent interpretation and enforcement of standards in the States and territories can be a source of frustration.

Figure 5 | Enforcement agencies used in each jurisdiction



5.4 Legislative and operational changes may improve the implementation and enforcement of food standards

Three reform ideas have been identified that could help drive greater consistency in the interpretation of food standards by the jurisdictions. These could be considered separately or in conjunction.

5.4.1 Reform idea 15 – Enhance FSANZ’s role in providing guidance about food standards within its current statutory remit

FSANZ could be resourced to provide comprehensive guidance about food standards within its current legislative remit. This could involve:

- **Including a statement of intent alongside food standards in the Food Standards Code** to describe what FSANZ wants to achieve in the writing of each food standard (akin to Explanatory Memoranda) which could provide basis for enforcement activities. The current definition of ‘standard’ in the Act – which excludes editorial notes and text identified as an example – could be changed to enable this.
- **Resourcing FSANZ to update and maintain industry guidelines** which provide advice on how industry can comply with food standards. This process could be led by industry, based on specific interpretive issues and requests for clarification.

5.4.2 Reform idea 16 – Provide for FSANZ to give binding interpretive advice on food standards

FSANZ’s role in interpreting food standards could be expanded through new legislative powers to provide binding interpretive advice about standards to jurisdictions and industry. This reform idea could be achieved through different mechanisms, such as:

- **Introducing compliance codes or advice** that can reliably be followed by stakeholders to ensure their compliance with food standards. ‘Deemed to comply’ provisions are commonly used in other regulatory schemes, including Worksafe Victoria and the Australian National Construction Code (see Table 14).

Table 14 | Worksafe Victoria's guidance powers, including compliance codes and National Construction Code's 'deemed to satisfy' provisions

Worksafe Victoria is the state's health and safety regulator and manager of Victoria's workers compensation scheme. It is established under the *Occupational Health and Safety Act 2004*. Under the Act it has a range of general powers, including to:

- make guidelines about how a provision would apply to a set of circumstances
- give advice on compliance to anyone who has a duty or obligation under the Act
- issue compliance codes to provide practical guidance to duty holders under the legislation.

Compliance codes provide, in effect, a deemed to comply route for regulated entities. While failure to comply with such a code does not give rise to liability, a person who complies with the code may be taken to have complied with the Act. This can provide more certainty for regulated entities about meeting their regulatory obligations.

The National Construction Code is a performance-based building and plumbing code that sets the minimum technical requirements for new buildings in Australia. As a performance-based code, a plumbing or drainage solution complies with the NCC if it satisfied the relevant Performance Requirements. There are multiple pathways for complying with the performance requirements of the code, for instance through:

- 'deemed-to-satisfy' provisions include explicit materials, components, design factors and solutions which, if followed, demonstrate compliance
- performance solutions are more general performance requirement for how the building or component must perform but does not include an obligation to adopt a specific material or method.

Multiple pathways for compliance are designed to promote flexibility and innovation, while ensuring that compliance obligations are readily understood by practitioners.

- **Introducing a power for FSANZ to make binding interpretations about food standards** either in response to an application or proposal, or on its own initiative. This could form the basis of a library of binding interpretations or rulings about the food standards which could provide legal protection to regulated entities and greater certainty for enforcement agencies.

This option would not necessarily require jurisdictions to recognise FSANZ's statutory power in legislation; jurisdictions could voluntarily refer to this advice to shape their enforcement activities. In the event that a compliance matter was heard in court, the court would be able to consider binding advice to inform their ruling.

The Australian Tax Office's (ATO's) model for providing binding advice about tax law could provide inspiration for a model for FSANZ (see Table 15).

Table 15 | The ATO's powers to make legally binding interpretive advice

The ATO has the power to provide binding interpretive advice about the laws it administers. Advice is generally in the form of a binding ruling which explains a taxpayer's obligations or entitlements under a provision of tax law. The regime for public, private and oral rulings was established in 2005 and expanded in 2010.

Individuals or businesses can seek a public, private or oral ruling by the Commissioner of Taxation and receive binding advice about how legislation should apply to a specific circumstance. The applicant can

then rely on that advice in a court of law, if required.

Advice provided through public rulings is collated and published. The ATO also publishes 'precedential ATO views' which are documented views about the interpretation of tax laws. These can assist individuals and businesses to comply with their obligations and can also inform enforcement approaches.

Precedential ATO views aim to ensure that decisions on interpretive issues are accurate and consistent over time.

5.4.3 Reform idea 17 – Enhance FSANZ's regulatory role by providing limited enforcement powers

FSANZ could undertake a broader regulatory role by being provided appropriate statutory powers in its legislation to enforce compliance with food standards. This could include enforcement of:

- food-health claims
- novel foods
- food products sold across state and territory borders within Australia; or traded between Australia and New Zealand.

This reform idea could provide a more fundamental change to drive greater consistency in enforcement of food standards and could use FSANZ's technical expertise to detect non-compliance with food standards. To be successful, FSANZ would need to have appropriate monitoring and enforcement powers, including the ability to compel the provision of information and apply sanctions in response to non-compliance. This would also require regulatory capability to be developed within FSANZ.

This function would need to be reflected in state, territory, Australian Government and New Zealand law. The roles and boundaries of FSANZ, individual jurisdiction and Australian Government regulators would need to be clearly articulated and agreed.

Some stakeholders have highlighted the independence of FSANZ as one of its greatest strengths. Of note, there are many other examples of entities that have a role in both setting regulatory rules and enforcing them, including the ACCC and the New Zealand Medicines and Medical Devices Safety Authority.

Discussion questions:

21. To what degree does inconsistent interpretation of food standards present an issue for the system? What are the types of problems that different stakeholder groups face as a consequence?
22. What would be the impact (positive, negative or otherwise) of implementing each of the reform ideas below? How could the outcome specified for each reform idea best be achieved?
 - Reform idea 15 – Enhance FSANZ's role in providing guidance about food standards within its current statutory remit
 - Reform idea 16 – Provide for FSANZ to give binding interpretive advice on food standards
 - Reform idea 17 – Enhance FSANZ's regulatory role by providing limited enforcement powers

5.5 The boundaries between food and medicine – and their respective regulatory frameworks – are not always clear

The food regulatory system interfaces with a range of other regulatory schemes, including consumer affairs, environmental protection, animal welfare and biosecurity. Food products may be regulated by some combination of these (and other) regulatory schemes. These interfaces can present challenges where there is not a consistent, shared understanding of what regulatory schemes a product should be regulated by. This can lead to products ‘falling between the cracks’ of regulation.

Relevant to this Review²⁹ is the ‘food medicine interface’.

5.5.1 The food-medicine interface is an enduring issue

Both foods and medicines can make claims about the relationship between a product and health outcomes. Regulatory arrangements for foods that make health claims are covered under the Act and Food Standards Code (discussed at section 5.5.3.) Therapeutic products (including medicines) are regulated under different schemes in Australia and New Zealand:

- In Australia, the Therapeutic Goods Administration (TGA) regulates therapeutic goods, including complementary medicines, under the *Therapeutic Goods Act 1989*. Complementary medicines, including nutritional supplements, are defined in the associated Regulations based on a number of designated active ingredients.
- In New Zealand, therapeutic products are regulated by the New Zealand Medicines and Medical Devices Authority (Medsafe) under the Medicines Act 1981 and associated amending acts and regulations. Medsafe also administers labelling and composition regulations for dietary supplements (such as vitamin and mineral tablets) under the Dietary Supplements Regulations 1985 (established under the Food Act 1981) while MPI is responsible for their manufacture.³⁰ Additionally, MPI administers a standard for supplemented food under the Food Act.³¹

The food-medicine interface arises where there is contention or ambiguity about the regulatory scheme under which a specific product is covered. This can lead to inadequate regulation, ineffective risk management and risks to health and safety (for example, see Table 16).

Stakeholders consulted to date note that this is a vexed issue that defies easy resolution. Over time, there has been significant growth in innovative and diverse products that purport to have health benefits. Such products may have features that resemble both medicines and foods, and challenge existing product categories that seek to draw a sharp distinction between foods and medicines.³²

²⁹ The food medicine interface is called out explicitly in provision 3b of the Terms of Reference for this Review.

³⁰ Currently, the Ministry of Health, with support from MPI, is developing a broader regulatory regime for natural health products that will supersede the Dietary Supplements Regulations.

³¹ A supplemented food is a food, but it has been modified in some way or had substances added to it so that it performs a physiological role.

³² For example, a US study from 2013 on ‘food-pharma convergence in medical nutrition’ notes that “industries within the health and life science sector are moving towards one another resulting in new industries such as the medical nutrition industry.”

Weenen, T et al 2013, ‘Food-Pharma Convergence in Medical Nutrition – Best of both Worlds’, available at: <<https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0082609>>

Table 16 | Issues at the food-medicine interface

A 2017 article³³ reported 'Kids Smart Vita Gummies' were listed with the Therapeutic Goods Administration (TGA) as a complementary medicine, yet a similar product 'Bioglan Omega 3 Fish Oil Kids Gummies' has not been listed with the TGA and may be classified as foods.

At a minimum, this blurry interface creates complexities in responding to complaints about food-medicine products. For example, multiple consumers have reported that their complaints about how products have been labelled have been continuously re-directed between regulators without decisive action³⁴.

5.5.2 Clear delineation of food and medicine defies a simple solution

Addressing issues at the interface of food and medicine requires a clear, sensible and consistent way to categorise different products that make health claims to ensure appropriate risk management and clear regulatory oversight. This is unlikely to be achieved through legislative changes alone. While clear definitions of 'food' and 'medicine' (and other related concepts such as 'health claim' and 'therapeutic claim') are necessary, they are unlikely to be sufficient given:

- industry innovation and the introduction of new products that make health claims and challenge any clear-cut definitions that attempt to delineate foods and medicines
- the lack of objective criteria to consistently (and in all cases) distinguish food from medicine
- context-specific consumer perceptions of whether a particular product is a 'food' or 'medicine' (or, indeed, some combination of both) that are informed by packaging, labelling, place of sale and other factors that vary on a case-by-case basis.

As a result, managing the food-medicine interface depends, in part, on a regulatory policy strategy that includes active collaboration and coordination between regulators.

This has been developed in recent years in both countries. In Australia, the Food Medicine Interface Guidance Tool (FMIGT) and protocol was developed by an ISFR/TGA working group and endorsed in 2014. It outlines how TGA and food regulators will work together when assessing a product at the interface of food and medicine. Australian stakeholders consulted to date have noted perceived shortcomings with the FMIGT, including the lack of an escalation framework and dispute resolution mechanisms and the step-by-step and piecemeal nature of the assessment.

In New Zealand, Medsafe has also developed a 'product categorisation decision tool' to help businesses understand how products are likely to be categorised and makes available online a searchable database of ingredients scheduled under the Medicines Act. MPI and Medsafe also meet regularly to discuss products at the food-medicine interface.

The regulatory practice approaches adopted by food and medicine regulators fall out of scope for the Review as they are not tied to the Act or FSANZ operations. There may be an opportunity however to address this (in part) through the concurrent review of the FRA.

³³ The Conversation. (2019). *Kids' vitamin gummies: unhealthy, poorly regulated and exploitative*. <https://theconversation.com/kids-vitamin-gummies-unhealthy-poorly-regulated-and-exploitative-76466>

³⁴ Harvey, K., Watson, W., & Stanton, R (2019). *When food meets medicine: reform needed*. MJA: <https://insightplus.mja.com.au/2019/15/where-food-meets-medicine-reform-needed/>

5.5.3 Limited oversight of food-health claims may contribute to the food regulatory system being seen as a 'path of least resistance'

Food businesses may make claims about the relationship between a food and health within the constraints set by the Act and Standard 1.2.7 of the Food Standards Code. There are two types of food-health claims that food businesses may make on labels or advertising about a food. These are:

- **general level health claims** refer to a food or substance in a food and its effect on health, excluding serious diseases. Food businesses are permitted to make general level health claims on the basis of more than 200 pre-approved food-health relationships in the Code. Businesses are also able to self-substantiate general level health claims but must notify FSANZ under the Standard. FSANZ does not assess, endorse or enforce these claims. Food businesses are required to establish a food-health relationship 'by a process of systematic review'.
- **high level health claims** refer to a food or substance in a food and its relationship to a serious disease or biomarker of a serious disease. High level claims are permitted under the Standard and must be based on a food-health relationship pre-approved by FSANZ. There are currently 13 food-health relationships that are pre-approved. Specific statutory processes for high level health claims variations are set out in the Act. New food-health relationships for high level health claims can be established following assessment of an application to change food standards which includes consideration by the High Level Health Claims Committee.

Anecdotally, some Australian stakeholders observe that making a general level health claim under the Food Standards Code is relatively less onerous than regulation of therapeutic goods. This can lead to businesses seeing the food regulatory system as a 'path of least resistance', given inconsistent approaches to monitoring and enforcement of these claims. Some food businesses will therefore seek to position their products as foods, and this can present real risks to consumers if products contain unsafe levels of certain ingredients, or if information is misleading or incorrect.

In New Zealand, MPI undertakes an in-depth evaluation of a 'dossier of evidence' to substantiate general level food-health claims. If a food-health relationship is not substantiated, a food business may be required to ask FSANZ to remove the notified food-health relationship. This provides more rigorous oversight than in Australia where there is no comparable assessment of such claims. New Zealand stakeholders raise specific concerns, however, about claims made in relation to dietary supplements which are not subject to the same degree of oversight. Currently, the Ministry of Health, with support from MPI, is developing a broader regulatory regime for natural health products, including dietary supplements.

An added complexity in Australia is different approaches to enforcement by the jurisdictions and different capability and capacity which can lead to different regulatory approaches. A recent study³⁵ found:

- substantial variations in the length of time for jurisdictions to investigate potential breaches of the health claims standard, ranging from 2-30 months
- inconsistencies in the evaluation of evidence dossiers and systematic literature reviews underpinned by inconsistent capacity of food regulators.

Stakeholders consulted to date note that there may be a general view that a systematic literature review will not be assessed by an enforcement agency unless a complaint is made.

FSANZ's role in the oversight of food-health claims is currently limited. FSANZ publishes notified food-health relationships on its website, although it has no role in validating these. Some stakeholders engaged

³⁵ *Key issues with Food and Medicine Interface* 2019, prepared by Department of Health and submitted for the Review.

to date have noted concerns that this approach may lead some consumers to mistakenly believe that this indicates FSANZ's endorsement.

FSANZ could potentially undertake a broader role in relation to food-health claims to support more consistent and rigorous oversight.

5.6 Three improvement opportunities have been identified to address issues at the food-medicine interface.

5.6.1 Reform idea 18 – Focus efforts on improving the food-medicine interface through regulatory practice

Under this Reform idea, efforts to improve the food medicine interface would focus on regulatory practice, in particular refining the guidance tools described above. This work would be progressed outside the scope of the Review.

5.6.2 Reform idea 19 – Broaden the role of FSANZ to assess general level health claims

Under this reform idea, FSANZ would undertake a broader role with respect to general level health claims in Australia that aligns and integrates with, or is informed by, the MPI's approach in New Zealand. This could seek to make regulation of such claims more rigorous and comparable with regulation of complementary medicines.

This reform idea could be operationalised in different ways:

- **Resourcing FSANZ to take a greater role working with businesses in pre-market entry phase** – FSANZ's role could be expanded to include assessment or evaluation of general level health claims. This could be achieved by amending the notification process in Standard 1.2.7 and by amending FSANZ's functions in the Act to include "*assessment of general level health claims made by food businesses*". FSANZ could assess general level health claims prior to market entry (i.e. as a pre-requisite for making the food-health claim) or through post-approval assessment (i.e. prohibiting claims that cannot be substantiated).
- **Providing greater support to food businesses to understand their obligations** – FSANZ could have a more hands-on role working with food businesses, especially small businesses, to understand their obligations when self-substantiating a general level health claim.
- **Providing for FSANZ to take on regulatory responsibility for health claims** – FSANZ could be responsible for enforcement of food-health claims (as discussed in Section 5.4.3 above).
- **Provide interpretive advice about food-health claims to jurisdictions and industry** – FSANZ could provide interpretive advice about health claims standards (consistent with the reform ideas discussed in Sections 5.4.1 and 5.4.2 above).

This reform idea could help to address issues that stakeholders engaged to date have raised about the food regulatory system being a 'comparably less onerous' than for therapeutic goods and, thus, a 'path of least resistance' for business.

This reform idea could also help to reduce inconsistent interpretation and enforcement of health claims standards by the Australian jurisdictions, especially if FSANZ took on an enforcement role.

On the other hand, this Reform idea may increase the compliance burden for industry and – depending on the regime for assessing general level health claims – could hamper innovation and the ability to bring products to market.

5.6.3 Reform idea 20 – Align definitions and powers in legislation between therapeutic goods and foods

Food is defined in s 5 of the FSANZ Act in broad terms which include “any substance or thing of a kind used, or represented as being for use, for human consumption” (s 5(1)(a)). This excludes therapeutic goods within the meaning of the *Therapeutic Goods Act* (s 5(2)).

Under the Act, the Australian Minister of Health may make a declaration of what is food after consulting FSANZ (s 6). This definition is adopted in each of the Australian states and territory food legislative schemes.³⁶ A similar definition is adopted in New Zealand’s *Food Act 2014* that makes specific inclusions and exclusions relevant to the New Zealand context, including anything declared by the Governor-General to be food for the purposes of the Act.

In Australia, the definition of ‘therapeutic goods’ in the *Therapeutic Goods Act* provides broader grounds for establishing a single source of truth on the definition of a therapeutic good. The definition excludes “goods for which there is a standard” under the FSANZ Act, as well as “goods which, in Australia or New Zealand, have a tradition of use as foods for humans in the form in which they are presented” (s 3(1)). The Secretary may declare that goods are or are not therapeutic goods for the purposes of the Act (s 7) and the Minister may exclude specified goods for the purposes of the Act (s 7AA).

The FSANZ Act and *Therapeutic Goods Act* are both currently administered by the Australian Minister for Health.

The definition of food in the FSANZ Act could be broadened to align with this in the following ways:

- **Provide for determination of what is not a food** – The Ministerial power to determine a product as a food under s 6 could be broadened to determine that a product is not a food for the purposes of the Act to specifically exclude items. The New Zealand Governor General already has this power under the *Food Act 2014*.
- **Provide for broader basis for interpretation of what constitutes a therapeutic good** – The provision within the Act that excludes therapeutic goods from the definition of ‘food’ could be broadened. This could mirror the language in the *Therapeutic Goods Act* to exclude goods which “have a tradition of use as therapeutic goods in the form in which they are presented.”

Discussion questions:

24. To what degree is the food-medicine interface and the oversight of health claims an issue for the system? What are the types of problems that different stakeholder groups face as a consequence?
25. What would be the impact (positive, negative or otherwise) of implementing each of the reform ideas below? How could the outcome specified for each reform idea best be achieved?
 - Reform idea 18 – Focus efforts on improving the food-medicine interface through regulatory

³⁶ There are slight variations from the FSANZ Act definition in some cases. For example, Queensland’s *Food Act 2006* includes “water, other than reticulated water” in its definition of food.

practice

- Reform idea 19 – Broaden the role of FSANZ to assess general level health claims
- Reform idea 20 – Align definitions and powers in legislation between therapeutic goods and foods

26. Are there other potential solutions relating to improving the food-medicine interface?

6 Operations

This section considers how FSANZ delivers its functions by analysing elements of its operations that are founded in the legislation. This includes its governance arrangements (including appointment process for Board members) and managing its revenue stream.

6.1 FSANZ's governance is enshrined in legislation

FSANZ is governed by a Board that is the accountable Authority for FSANZ and has statutory responsibilities for developing food standards. The Board comprises 12 members with a broad range of expertise required by the Act. Three members are nominated by the New Zealand lead minister on the Forum. Board members are appointed for a maximum of eight years, comprised of two four-year terms.

The Board has specific non-delegable duties in relation to decisions about draft standards or variations (set out in s 150).

The Act also establishes the CEO who is appointed by the Board and who is responsible for the day-to-day administration of FSANZ and control of its operations.

6.1.1 Statutory requirements around Board composition, nomination and appointment processes could be improved

The Board of FSANZ provides an independent collective decision-making forum for governing FSANZ and making decisions on draft standards. The FSANZ Board is *representative* in nature: more than half (7-out-of-12 members) are nominated by different organisations with specific expertise and role in the food system, including industry, public health and consumer interests. The list of organisations that can provide nominations for different Board members is prescribed in the Regulations.

It is common for Boards with regulatory functions to have some members nominated by external stakeholder groups. Representative Boards can, however, raise concerns in relation to regulatory independence or regulatory *capture* if entities with statutory decision-making responsibilities are seen to unduly represent the interests of groups that they regulate.³⁷

To date, stakeholders have not raised specific concerns about regulatory independence in relation to the Board, however a range of issues around FSANZ's current governance arrangements have been noted:

- **Nomination and appointment processes are cumbersome.** The legislated requirement³⁸ to seek input from a large number of prescribed organisations, followed by approval from the Forum, can lead to lengthy nomination and appointment processes that are resource intensive without necessarily providing additional value to member selection. These reportedly can take up to 15-18 months.
- **Current arrangements may not lead to an optimal skill mix.** An intended strength of the FSANZ Board is breadth of expertise that spans many elements of the food system. The Act sets out an

³⁷ The Second Reading Speech to the Bill that established FSANZ make explicit mention of the Board's independence, stipulating that Board members are "*not representatives of the various interest groups.*"

³⁸ Per s 116(1)(f) and (g), the Minister must seek appointment nominations from certain organisations and public bodies prescribed in the Regulations to determine if the person is suitably qualified for the appointment.

extensive list of skills that Board members have to demonstrate expertise “in one or more of”.³⁹ However, the Act does not provide for ensuring breadth of expertise on the Board and neither the Chairperson nor the CEO currently has a formal input role to selection of new Board members. These arrangements make it difficult to address identified capability gaps in a strategic way or assemble a Board with an optimal set of capabilities.

- **The Board’s size can inhibit timely, efficient and responsive governance activities.** The FSANZ Board comprises 12 members. A Board offers opportunity for a collective and independent decision-making process that ensures a breadth of expertise and perspectives are brought to bear on decisions. This needs to be balanced with ensuring a manageable size that facilitates effective decision making and does not impose undue fiscal burden through Board member remuneration or the costs involved in Board meetings.

6.2 Legislative change could support more efficient and effective governance for FSANZ

Three reform ideas have been identified to strengthen FSANZ’s internal governance arrangements.

6.2.1 Reform idea 21 – Streamline Board appointments and nominations

Statutory processes setting up the FSANZ Board, including nomination and appointment processes, could be refined to support more efficient on-boarding and a more clearly defined skills-based approach to appointing Board members. Key changes could include:

- **Streamlining nomination and appointment processes.** This could be achieved by reducing the number of members that are appointed by external organisations, removing the statutory requirement for the Minister to seek nominations from prescribed organisations, and/or reducing the Forum’s role in signing off on all Board appointments.
- **Adopting a skills-based approach to member appointments.** The current list of skills that different Board members are required to have expertise in as a condition of membership could be replaced by a simpler provision requiring that the Minister appointing the Board member must, so far as is practicable, ensure members have skills, experience and knowledge, including in food regulation, consumer affairs, food science, public sector governance and accountability, and the food industry. The Chairperson and/or CEO could have a formal input or decision-making role. Consideration could be given to appropriate Australia and New Zealand-specific contextual knowledge.

6.2.2 Reform idea 22 – Establish minimum term length for Board members

The Act provides for a maximum term of four years for Board members (with the option of a second term) but does not include a minimum term length. This can create challenges in ensuring continuity of Board membership, when terms vary in length or expire concurrently. Amending the Act to establish a minimum term length could provide greater certainty and aid planning for filling Board membership vacancies.

³⁹ This is supported through provisions in s 116 (S 116(2) to S 116(5)) that set out a list of relevant skills for each Board member and requires that each has expertise in one or more fields. The lists of relevant skills are extensive, including a range of scientific disciplines, regulation and government, and industry expertise.

6.2.3 Reform idea 23 – Reduce Board size

The Board could be consolidated to eight people, including a Chairperson and seven members, several of whom could be appointed by the New Zealand Minister on the Forum. This could support more efficient decision-making and reduce the fiscal burden associated with a 12-person Board. Consideration would need to be given to ensure breadth of expertise is not compromised.

The CEO could cease to be a member of the Board. This arrangement may be particularly desirable if reform ideas to allow the Board to delegate decisions about food standards to the CEO are pursued (as detailed in Section 4.4.2).

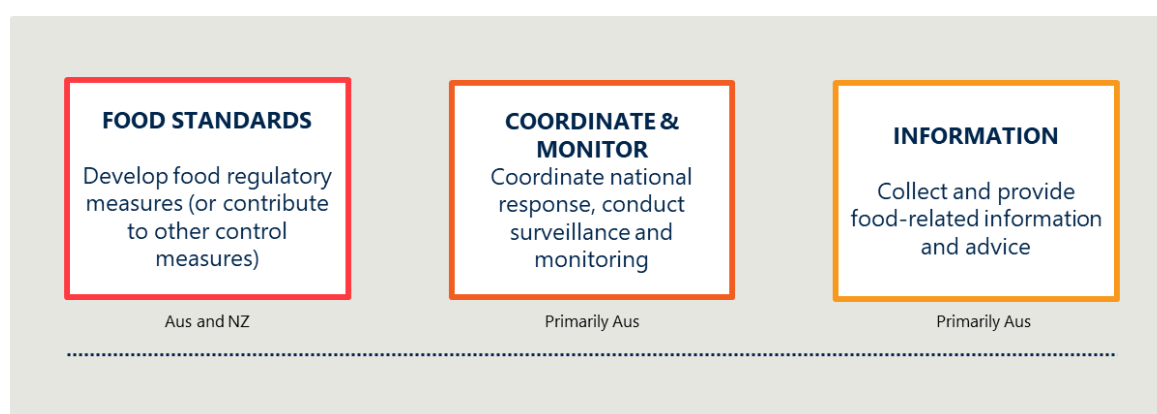
Discussion questions:

27. To what degree are FSANZ's governance arrangements an issue for the system? What are the types of problems that different stakeholder groups face as a consequence?
28. What would be the impact (positive, negative or otherwise) of implementing each of the reform ideas below? How could the outcome specified for each reform idea best be achieved?
 - Reform idea 21 – Streamline Board appointments and nominations
 - Reform idea 22 – Establish minimum term length for Board members
 - Reform idea 23 – Reduce Board size.
29. Are there other potential solutions relating to FSANZ's governance arrangements?

6.3 FSANZ has multiple priorities and constrained resources

FSANZ has a range of competing priorities about where it allocates its resources. Its annual report categorises its work into three key groups (see Figure 6). In addition, FSANZ manages project work, such as contributions to the Australian Health Survey and Australia Total Diet Survey and critical food safety incident investigations.

Figure 6 | FSANZ's core functions, as categorised in its annual report



FSANZ is required under by the Act to develop a three year forward plan for applications, proposal and types of applications and proposals on which it intends to develop standards or variation to standards. This provision requires that FSANZ review and update the plan at least every three months.

6.3.1 Funding constraints underpin FSANZ's resourcing model

FSANZ is primarily funded through a Commonwealth Government appropriation and receives additional funding from the New Zealand Government, special projects and through cost recovery. Australian states and territories do not directly contribute to FSANZ's revenue stream.

In recent years, FSANZ's operating budget has declined in real terms, which has forced FSANZ to prioritise its resources to process applications within statutory timeframes.

Specifically, while all applications must be processed within set timeframes, the Act also provides for applicants to expedite applications by paying a fee. This provision places a five-business day timeframe on providing public notice of an application and commences the statutory timeframe for resolving the application. In contrast, for unpaid applications, the statutory timeframe for assessment is not triggered until the assessment itself commences. Proposals, on the other hand, are not subject to statutory timeframes and therefore are often relatively slow to progress.

This approach does not necessarily deliver the best value to the Australian and New Zealand community; applications may have a small number of beneficiaries outside the initial applicant, while proposals often have system-wide impacts and stakeholders are highly invested in outcomes.

FSANZ's ability to deliver its functions in a timely and effective way is ultimately a question of resourcing, and what resources can be secured within FSANZ's funding envelope. For example, based on current funding arrangements, FSANZ has capacity to progress a set number of proposals each year. FSANZ and the Forum could work together more strategically to agree priority proposals (as per Section 5.2.1). FSANZ could deliver more – including processing higher volumes of proposals and applications and undertaking other statutory functions in a timely and responsive way – with additional funding and resources.

6.3.2 Cost recovery mechanisms can be considered as part of the Review

Funding arrangements are largely agreed outside of the Act and are therefore out of scope for this Review. However, a separate, target review on this topic may be warranted - this could include re-evaluating the overall contribution made by governments; the appropriate distribution of costs between Australia and New Zealand⁴⁰ and the potential for states and territories to directly contribute to project-specific funding.

Cost recovery mechanisms on the other hand are captured within the Act and therefore can be addressed as part of the Review.

Currently, FSANZ can collect fees from industry if a variation to a food standard would bestow an exclusive capturable commercial benefit upon the applicant (s 27(c)); or, if the applicant elected to expedite an application (s 27(d)).

Cost recovery makes up only about two percent of FSANZ's total revenue stream. On the other hand, similar bodies to FSANZ such as the TGA and APVMA are primarily or solely funded through cost recovery. While they undertake different and more high-volume work, this illustrates that broader avenues for cost recovery could be considered.

FSANZ currently undertakes significant work with industry for which it is not currently remunerated. For example, pre-application assistance and advice can be highly resource intensive and may begin long

⁴⁰ Reviewing the contributions made by Australian and New Zealand Governments should also consider any new functions FSANZ may take on as a consequence of this Review. It is important that FSANZ's resources are allocated in such a way that meet the needs of both Australia and New Zealand.

before an application is eventually submitted to FSANZ. Similarly, there may be a market for FSANZ to do more to support interpret food standards (see Section 3.1.3).

Expanding the provisions for cost-recovery within the Act may be a viable mechanism for strengthening FSANZ's revenue stream (albeit, by a small margin).

Any additions would need to be consistent with Australian and New Zealand government policy in relation to cost recovery.⁴¹ This includes ensuring that it does not create a risk of regulatory capture, where the independence of FSANZ is challenged by 'services bought' by industry. It must also balance benefits with the risks such as the additional compliance burden, particularly for small businesses, and the potential displacement or disruption of private markets, for example, those that currently exist to support food businesses interpret food standards.

6.4 There are opportunities for legislative and operational reform to ensure adequate resourcing for FSANZ

Two reform ideas have been identified to address resourcing constraints faced by FSANZ by expanding its ability to recover costs for certain activities. These could be considered separately or in conjunction.

6.4.1 Reform idea 24 – Expand scope of applications for which FSANZ can recover costs

The current cost recovery model could be expanded to a greater proportion of applications by amending s 146 of the Act. This could include all or a broader subset of applications. This reform idea could provide some limited increase in business revenue, but this would be minimal given the small number of applications that FSANZ processes each year. This also creates an additional regulatory burden on food businesses.

6.4.2 Reform idea 25 – Provide for limited expansion of scope of activities for which FSANZ can recover costs

The Act could be amended to expand permitted cost recovery activities to include some activities which FSANZ currently – or could – perform. This could include pre-application assistance that is provided by FSANZ to industry free of charge currently, or the provision of interpretive advice on food standards. This reform idea would impose additional costs on industry and other stakeholders that currently receive services from FSANZ.

Discussion questions:

30. To what degree does FSANZ's approach to setting its own workplan and resourcing its work present an issue for the system? What are the types of problems that different stakeholder groups face as a consequence?
31. What would be the impact (positive, negative or otherwise) of implementing each of the reform

⁴¹ This includes the *Australian Government Charging Framework* (developed in 2015) which is supported by the *Australian Government Cost Recovery Guidelines* and the *Governance, Performance and Accountability (Charging for Regulatory Activities) Order*.

ideas below? How could the outcome specified for each reform idea best be achieved?

- Reform idea 24 – Expand scope of applications for which FSANZ can recover costs
- Reform idea 25 – Provide for limited expansion of scope of activities for which FSANZ can recover costs

32. Are there other potential solutions relating to FSANZ's operations?

7 Key reflections

This scoping paper has set out a number of issues in the system that fall under five key focus areas. A wide range of reform ideas have also been presented. As the Review progresses, there is a need to prioritise issues for resolution, and better develop reform opportunities that are practical, implementable and economical.

Discussion questions:

33. What are the top 2-3 most pressing issues to resolve through change to the Act and associated operations and responsibilities of FSANZ?
34. Are there key issues or challenges related to FSANZ and the Act that are not represented in this scoping paper?
35. What other reform ideas should be considered to address the issues identified in the paper, assuming no resource constraints?

8 Next steps

This scoping paper will be open for public submissions from 5 October 2020 to midday AEST 16 November 2020. Submissions received will be considered and thematically analysed to further refine the issues and potential reform ideas identified.

This will inform and support further consideration of more detailed reform options to address key challenges raised by the Review, including targeted stakeholder consultation.

Findings from written submissions and additional consultation will be collated into a Regulatory Impact Statement, which will be used to inform any amendments to the FSANZ Act. The Department of Health, in collaboration with New Zealand, will lead the legislative amendment process.

Appendix A Review Terms of Reference

Table 17 provides the full Terms of Reference for the Review.

Table 17 | Review Terms of Reference (available online)

Review into the *Food Standards Australia New Zealand Act 1991*

TERMS OF REFERENCE

1. The review will include a comprehensive examination of the effectiveness of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act) and the associated operations and responsibilities of Food Standards Australia New Zealand (FSANZ). It will include consideration of the economic efficiency of regulation, recognising the importance of the food industry to regional communities and the broader economies of both Australia and New Zealand. The review will include findings and recommendations for any reforms. The final report from the review will be provided to the Australian minister responsible for FSANZ, who will consider the report/review in partnership with the New Zealand Minister for Food Safety and consult with state and territory food ministers through the Australia and New Zealand Ministerial Forum on Food Regulation (the Forum).

Scope

2. The review will include the FSANZ Act and FSANZ operations, with a focus on areas identified as being inconsistent with best practice regulation and standard setting. The review should consider and make recommendations on the appropriateness of FSANZ Act legislation, in particular:
 - a. The FSANZ assessment process to ensure it is fit for purpose and outcomes based and promotes an efficient and internationally competitive food industry. This work should include:
 - o ensuring any proposed changes to the regulatory system imposes the least burden on business to achieve the stated objectives of the regulation and specific consideration is given to the impact on small businesses; and
 - o revision of the interface between the regulator and business, i.e. the digital or paper systems used to support the assessment.
 - b. An optimal operating model for FSANZ, the roles and functions of FSANZ including consideration of FSANZ undertaking a greater role as a regulator.
 - c. Cost recovery models for industry-initiated work.
 - d. Decision making processes, including the role of the CEO, FSANZ Board and Ministers.
 - e. Best practice board appointment processes.
3. The review should consider and make recommendations on the operational functions of FSANZ, in particular:
 - a. The timeliness of work undertaken and relative priority of the FSANZ work plan including consideration of the risk proportionality and international harmonisation of risk assessments and standards.
 - b. The operation and effectiveness of the Food-Medicine Interface, including the effectiveness of regulation around nutrition supplements.
 - c. FSANZ as an independent agency and appropriate resourcing.
4. The review should also consider what wider role FSANZ as a joint body could take across Australia and New Zealand and in Australia only, by considering issues and making recommendations in relation to FSANZ's potential role including (but not limited to):
 - a. Enforcement of food standards – noting concerns around a lack of consistent implementation of standards across jurisdictions.
 - b. Emerging issues – such as food fraud and food crime.
 - c. Food safety – noting consumers' and industry's desire for one 'Face of Food Safety' that produces a unified national approach to raising awareness and responding to food safety issues (Australian context only).
 - d. Food safety research – including facilitating collaboration on research relating to food safety.
 - e. Communication of food standards to industry and consumers – including a greater role in providing advice on interpretation of food standards.

- f. Undertaking education campaigns – in alignment with Priority 1 and Priority 2 of the Food Regulation system.

The review will provide an indication of the potential role of FSANZ in both Australia and New Zealand and relative impact of the recommendations for Australia and New Zealand.

Out of scope

5. The review will not include other food legislation and agreements, such as the Food Regulation Agreement, the Food Treaty, or the Model Food Act. However, should issues with these instruments be identified, they may be considered separately.

Process

Stakeholder engagement

6. Wide consultation will be undertaken as part of the review, including with government, consumer, public health, and industry stakeholders along the supply chain.

Legislative amendments

7. In accordance with Article 4(4) of the Treaty, no amendments to the FSANZ Act will be introduced without effective consultation with New Zealand.

Principles

Alignment with Priority 3 of the food regulation system

8. The review will complement the objectives of Priority 3 of the food regulation system, as agreed by the Forum in April 2017: *to maintain a strong, robust, and agile food regulation system*. The central focus of this work is applying best practice regulatory approaches, with the objectives of improving timeliness, ensuring the food regulation system is responsive, and provides a unified voice regarding food safety and applying processes proportional to risk. Under the Priority 3 program of work, the Food Regulation Standing Committee is concurrently considering wider reforms to the food regulatory system (including the Food Regulation Agreement and the Model Food Act). This review will aim to align with and complement the broader Priority 3 work.

Management

9. The Australian Government Department of Health in consultation with the Australian Government Department of Agriculture, Water and the Environment will manage the review through an independent consultant, in partnership with the New Zealand Government and in consultation with FSANZ, and Australian States and territories.

Appendix B FSANZ Act Review Steering Committee members

Table 18 outlines membership of the FSANZ Act Review Steering Committee.

Table 18 | FSANZ Act Review Steering Committee members

Organisation	Member
Australian Government Department of Health (Chair)	Tiali Goodchild
Australian Government Department of Agriculture, Water and the Environment	Nicholas Dowie, Assistant Secretary, Food and Supply Chain Branch
New Zealand Ministry for Primary Industries	Bryan Wilson, Deputy Director-General New Zealand Food Safety Philip Houlding, Director, International Policy
Food Standards Australia New Zealand	Mark Booth, Chief Executive Officer
Department of Prime Minister & Cabinet	Bernard Fischer, Advisor, Economic Division



ABOUT NOUS

Nous Group is an international management consultancy operating in 10 locations across Australia, the UK and Canada. For over 20 years we have been partnering with leaders to shape world-class businesses, effective governments and empowered communities.

A dark blue world map graphic with white dots representing cities, located in the bottom left corner of the page.

bold
performance & influence
engaging

400

PEOPLE

10

LOCATIONS

3

COUNTRIES

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